DOCKET NO: 248993US23

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF	:
JIM THRELKELD	: EXAMINER: MERCIER, MELISSA S.
SERIAL NO: 10/785,060	:
FILED: FEBRUARY 25, 2004	: GROUP ART UNIT: 1615
FOR: METHOD FOR PROVIDING ANTIMICROBIAL COMPOSITE YARNS, COMPOSITE FABRICS AND ARTICLES MADE THEREFROM	:

APPEAL BRIEF

This is an appeal to the Board of Patent Appeals and Interferences under 35 U.S.C. §134 taken from the March 4, 2010, Final Rejection of Application 10/785,060, filed February 25, 2004. A Notice of Appeal was timely filed on August 4, 2010, with two extensions of time. This Appeal Brief is timely filed with two extensions of time.

STATEMENT OF REAL PARTY IN INTEREST

The real party in interest in this appeal is Supreme Corporation, having an address of 325 Spencer Road, Conover, North Carolina 28613, USA, by virtue of an assignment recorded on August 17, 2004, at reel 015706 and frame 0554.

STATEMENT OF RELATED APPEALS AND INTERFERENCES

Appellants, Appellants' legal representative, and assignee, are aware of no appeals, interferences, judicial proceedings, or cases that are related to, directly affect or would be directly affected by, or have a bearing on the decision of the Board of Patent Appeals and Interferences in this appeal.

STATUS OF CLAIMS

Claims 19-31, 33 and 34 are pending in this application.

No claims are allowed.

No claims are withdrawn.

No claims are objected to.

Claims 1-18 and 32 were previously canceled.

Claims 19-31, 33 and 34 are finally rejected.

Claims 19-31, 33 and 34 are herein appealed.

STATUS OF AMENDMENTS

No amendments to the claims have been requested after the Final Office Action dated March 4, 2010.

SUMMARY OF THE CLAIMED SUBJECT MATTER

Independent Claim 19 is directed to a method for providing antimicrobial properties to a composite item, comprising (i) immersing a composite item in an aqueous bath comprising an organic antimicrobial agent, wherein said organic antimicrobial agent is silicone based quaternary ammonium salt that is a copolymer of a long chain (C_{12}-C_{20}) alkyldimethylaminotrihydroxysilylpropyl ammonium halide and a chloroalkyltrihydroxy-silane; (ii) separating the immersed composite item from the bath; and (iii) drying the separated composite item at a temperature of from 50-90°C, wherein the composite item is a member selected from the group consisting of composite yarns, composite fabrics and composite articles; wherein the resulting composite item retains antimicrobial properties for at least 40 wash cycles; and wherein the antimicrobial properties can be regenerated after one or more uses by contacting the treated item with a hypochlorite solution. (Claims Appendix, Claim 19) (Evidenced by page 3, lines 13-20; page 5, lines 22-27; page 5, line 32 to page 6, line 4; page 7, lines 20-23; and page 8, lines 13-18 of the specification).

Claims 20-31, 33 and 34 depend directly or indirectly from Claim 19. Dependent Claims 20-31, 33 and 34 stand or fall with independent Claim 19.

There are no claims with means or step plus function language on appeal.

GROUNDS OF REJECTION TO BE REVIEWED

Claims 19-31, 33 and 34 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over Omura (US 6,384,254) in view of Smith III et al. ("Smith" US 6,759,127).

ARGUMENT

The Examiner has erred in concluding that the claimed invention would have been obvious.

The claimed invention relates to a method for providing antimicrobial properties to a composite item, said method comprising: **(i)** immersing a composite item in an aqueous bath comprising a particular organic antimicrobial agent (see claim 19 for details regarding the organic antimicrobial agent); **(ii)** separating the immersed composite item from the bath; and **(iii)** drying the separated composite item at a temperature of from 50-90°C; wherein **(a)** the composite item is a member selected from the group consisting of composite yarns, composite fabrics and composite articles; **(b)** the resulting composite item retains antimicrobial properties for at least 40 wash cycles; and **(c)** the antimicrobial properties can be regenerated after one or more uses by contacting the treated item with a hypochlorite solution.

The Examiner has alleged that the above-described claimed method would have been obvious in light of Omura's process as used with the antimicrobial agent of Smith. However, Appellants point out that neither Omura nor Smith disclose the claimed drying temperature of 50-90°C (see (iii) above). Instead, Omura discloses a drying temperature of "about 100 to 150°C" (col. 8, lines 15-17) and exemplifies only one temperature within this range, i.e., 135°C (col. 11, line 57). In addition, Omura discloses in the examples that the treated and dried cloth is further "heat treated at 165 °C for 2 minutes" (col. 11, lines 57-58). Accordingly, Omura suggests drying temperatures that are *higher* than 100°C, not lower than

100°C like that claimed. Lastly, Appellants point out that Smith discloses a drying temperature of "between about 320°F and 420°F" (col. 4, lines 12-14) which is equivalent to about 160-215°C. Given the above-noted disclosures of both Omura and Smith, it is clear that neither of the cited references disclose the claimed drying temperature of 50-90°C.

Furthermore, Appellants point out that neither Omura nor Smith disclose the claimed retaining of antimicrobial properties for at least 40 wash cycles (see (b) above). Omura only discloses that "[t]he thus treated cloth was laundered ten times in accordance with the 103 method of JIS L-0217" (col. 11, lines 58-60) before providing the "bacteria loss after washing (%)" results in the following table. Omura fails to disclose results for 40 or more wash cycles and also fails to provide a comparison of the 10-wash results with 1-wash results; therefore one cannot determine from Omura if the bacteria loss results are reduced or retained (as claimed) after repeated washings. Lastly, Smith is silent on performance after wash cycles, nevermind repeated wash cycles of 40 or more as claimed. Accordingly, neither of the cited references disclose the claimed retaining of antimicrobial properties for at least 40 wash cycles.

In addition, Appellants point out that both Omura *and* Smith are silent on the claimed regeneration of the antimicrobial properties by contacting the item/article with a hypochlorite solution (see (c) above). What's more, the Office has failed to specifically address this limitation of the independent claim in the Final Office Action dated March 4, 2010, or the Office Action prior to that dated May 13, 2009. Accordingly, the Examiner has either not examined this limitation or is suggesting that the claimed regeneration limitation is somehow inherent to the cited references. Either way, the Examiner has erred.

If the Examiner has not examined this limitation, she has not met her obligations under M.P.E.P. 707.07 for "completeness" of an Examiner's action. If the Examiner is

suggesting inherency, Appellants submit that there is no sound basis for such a finding for at least the following reasons.

The fact that a certain result or characteristic may occur or may be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999)(citations omitted). An invitation to experiment is not an inherent disclosure. *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1367 (Fed. Cir. 2004).

Finally, *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990), instructs "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." In this case, the Examiner has not provided a basis in fact and/or technical reasoning to support a finding that "the antimicrobial properties can be regenerated after one or more uses by contacting the treated item with a hypochlorite solution" as recited in Appellants' claimed process (see last two lines of claim 19) *necessarily* flows from the disclosures of Omura and/or Smith.

Accordingly, Appellants submit that since neither of the cited references disclose the claimed regeneration with a hypochlorite solution, and since the Office has failed to provide a single sufficient rationale of obviousness for this limitation (including an inherency-based rationale), Omura and Smith, alone or in combination, do not render obvious the claimed

process "wherein the antimicrobial properties can be regenerated after one or more uses by contacting the treated item with a hypochlorite solution" (last two lines of claim 19).

In view of the foregoing, and given that neither Omura nor Smith disclose the claimed drying temperature of 50-90°C (see (iii) above), the claimed retaining of antimicrobial properties for at least 40 wash cycles (see (b) above), and/or the claimed regeneration with a hypochlorite solution (see (c) above), Appellants submit that a *prima facie* case of obviousness over the claimed invention does not exist, and that the Examiner has erred in concluding otherwise.

Notwithstanding the above and assuming *arguendo* that a *prima facie* case of obviousness over the claimed invention does exist with respect to the combination of Omura and Smith, Appellants offer the following additional remarks regarding the non-obvious nature of the claimed invention.

The Examiner has made the following allegations: "it would have been obvious to one of ordinary skill in the art to utilize a lower temperature in order to dry the fabrics" and "it would be well within the knowledge of the skilled artisan to use a lower temperature for a longer time or a higher temperature for a short time" (Final Office Action dated March 4, 2010, page 6, last paragraph). In other words, the Examiner is alleging that lower temperature/longer time is interchangeable with higher temperature/shorter time.

Appellants submit that even if these allegations were accurate/true, one skilled in the art would *not* have expected to obtain a different result by merely interchanging lower temperature/longer time for the references' higher temperature/shorter time. However, the claimed invention which uses a lower drying temperature range has done just that, i.e., has provided a different result (e.g., improved percent reduction in bacteria).

Omura discloses that the "bacteria loss after washing" is only 65 to 97% when the method disclosed by Omura is used (see Table 4 in col. 12) - the method of Omura being disclosed as having "drying conditions [which] include about 100 to 150°C" (col. 8, line 15).

In contrast, the Declaration by Mr. Threlkeld (filed with the Office on January 13, 2010) shows that when the *claimed* method is practiced an improved percent reduction of bacteria of "99.99%" and ">99.99%" was observed after initial washing and drying (see Tables 1 and 2 respectively of the Declaration), and an improved percent reduction of bacteria of "99.5%" was observed after repeated washing and drying (see Table 2 of the Declaration).

Furthermore, and as the Declaration states:

> "One of ordinary skill would not expect to achieve such activity using the present invention antimicrobial agent under such mild treatment conditions. The above results are particularly surprising given the teachings of Smith III that such an antimicrobial agent requires much higher temperatures of drying in order to provide the treated article with antimicrobial properties."

Accordingly, not only are the improved results of Appellants' claimed process that uses a drying temperature range of 50-90°C neither disclosed nor suggested by Omura, but said improved results are unexpected in light of "such mild treatment conditions."

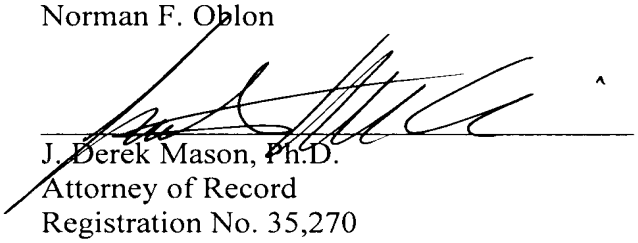
Accordingly, given the unexpectedly improved percent reduction in bacteria obtained by the claimed invention which uses a drying temperature range of only 50-90°C, Appellants submit that Omura, even in combination with Smith, fails to render obvious the claimed invention. Thus, Appellants assert that the Examiner has erred in concluding that the claimed invention is obvious over the cited combination of Omura and Smith.

CONCLUSION

For the reasons stated herein, Appellants submit that the combination of Omura and Smith fails to render obvious the claimed invention. Therefore the final rejection of Claims 19-31, 33 and 34 under 35 U.S.C. §103(a) as being unpatentable over Omura in view of Smith should be reversed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, L.L.P.
Norman F. Oblon



J. Derek Mason, Ph.D.
Attorney of Record
Registration No. 35,270

Justine M. Wilbur
Registration No. 59,678

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413 -2220
(OSMMN 07/09)

CLAIMS APPENDIX

Claims 1-18 (Canceled).

Claim 19: A method for providing antimicrobial properties to a composite item, comprising:

immersing a composite item in an aqueous bath comprising an organic antimicrobial agent, wherein said organic antimicrobial agent is silicone based quaternary ammonium salt that is a copolymer of a long chain (C_{12}-C_{20}) alkyldimethylaminotrihydroxysilylpropyl ammonium halide and a chloroalkyltrihydroxysilane;

separating the immersed composite item from the bath; and

drying the separated composite item at a temperature of from 50-90°C,

wherein the composite item is a member selected from the group consisting of composite yarns, composite fabrics and composite articles;

wherein the resulting composite item retains antimicrobial properties for at least 40 wash cycles;

wherein the antimicrobial properties can be regenerated after one or more uses by contacting the treated item with a hypochlorite solution.

Claim 20: The method of claim 19, further comprising the step of reusing the bath in a further immersing step on a different composite item.

Claim 21: The method of claim 19, wherein said composite item is a composite yarn.

Claim 22: The method of claim 19, wherein said composite item is a composite fabric.

Claim 23: The method of claim 19, wherein said composite item is a composite article.

Claim 24: The method of claim 23, wherein said composite article is a member selected from the group consisting of gloves, aprons, socks, filters, shirts, pants, undergarments, and one-piece jumpsuits.

Claim 25: The method of claim 21, wherein said process is a continuous process.

Claim 26: The method of claim 21, wherein said process is a batch process and said composite yarn is in a form of composite yarn wound on a bobbin.

Claim 27: The method of claim 22, wherein said process is a continuous process.

Claim 28: The method of claim 22, wherein said process is a batch process and said composite fabric is in a form of composite fabric wound on a roll.

Claim 29: The method of claim 19, wherein said organic antimicrobial agent is present in said bath in an amount of from 0.1-2 % by weight of the total bath.

Claim 30: The method of claim 19, wherein said silicone based quaternary ammonium salt is a copolymer of octadecylaminodimethyltrihydroxysilylpropyl ammonium chloride and chloropropyltrihydroxysilane.

Claim 31: The method of claim 23, wherein said immersing step is performed in a household clothes washer and said drying step is performed in a household clothes dryer.

Claim 32 (Cancelled).

Claim 33: The method of claim 19, wherein said drying step is performed at a temperature of from 70-90°C.

Claim 34: A composite item selected from the group consisting of composite yarns, composite fabrics and composite articles, having antimicrobial properties and prepared by the method of claim 19.

EVIDENCE APPENDIX

Affidavits and Declarations

The Declaration by Mr. Threlkeld filed with the Office on January 13, 2010 is relied upon in support of the patentability of the claims in this appeal (a copy of which is submitted herewith).

Other Evidence

In re Rijckaert, 9 F.3d 1531 (Fed. Cir. 1993).

In re Robertson, 169 F.3d 743 (Fed. Cir. 1999).

Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354 (Fed. Cir. 2004).

Ex parte Levy, 17 USPQ2d 1461 (Bd. Pat. App. & Inter. 1990).

RELATED PROCEEDINGS APPENDIX

None.

Docket No.: 248993US23

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: GROUP: 1615

Jim THRELKELD et al.

SERIAL NO: 10/785,060 EXAMINER: MERCIER, MELISSA S

FILED: February 25, 2004

FOR: METHOD FOR PROVIDING ANTIMICROBIAL COMPOSITE YARNS, COMPOSITE FABRICS AND ARTICLES MADE THEREFROM

DECLARATION UNDER 37 C.F.R. § 1.132

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

Sir:

Now comes _James Threlkeld who deposes and states that:

1. I am a graduate of Wake Forest College and received my BS degree in the year 1959.

2. I have been employed by Chemstrand Research Center,Fycon Technolgy and Others for 50 years as a Chemist in the field of Textiles.

3. The following experiments were carried out by me or under my direct supervision and control.

Fabrics were prepared from composite yarn having the following construction:

Core: Fiberglass #450 (nominal 100 denier) and ultra-high molecular weight polyethylene (nominal 400 denier)

1st wrap: 70 denier polyester

2nd wrap: 70 denier polyester

The fabric was then treated in accordance with the present invention using a silicone based quaternary ammonium salt antimicrobial agent that is a copolymer of a long chain (C_{12}-C_{20}) alkyldimethylaminotrihydroxysilylpropyl ammonium halide and a chloroalkyltrihydroxysilane, with the drying step being performed at a temperature of 90°C or less.

The resulting treated fabric was tested in accordance with ASTM E2149-01 against three different bacteria (E. coli; S. Aureus; methicillin resistant S. Aureus) and in accordance with AATCC 30-III against one fungus (A. niger), and compared against untreated samples of the same fabric. The results are reported below.

TABLE 1 (Bacterial testing)

	Microbiological Analysis (according to ASTM E2149-01)		
	Initial Concentration	Final Concentration	Percent Reduction
S. aureus ATCC 6538			
Untreated fabric	1.33×10^5 / ml	1.15×10^5 / ml	0%
Treated fabric	1.33×10^5 / ml	$<1.0 \times 10^1$ / ml	>99.99%
Inoculum control	1.33×10^5 / ml	1.22×10^5 / ml	0%
Methicillin resistant S. aureus			
Untreated fabric	1.52×10^5 / ml	1.6×10^5 / ml	0%
Treated fabric	1.52×10^5 / ml	$<1.0 \times 10^1$ / ml	>99.99%
Inoculum control	1.52×10^5 / ml	1.55×10^5 / ml	0%

TABLE 2 (multi wash/dry test using E. coli)

Description	Microbiological Analysis		Chemical Analysis			
	ASTM E2149-01		Uniformity		% Extraction	
	Initial	5X	Initial	5X	Initial	5X
Untreated	<20%	28%	No Color	No Color	12%	20%
Treated	99.99%	99.5%	Excellent	Excellent	97%	86%

ASTM E2149-01
1.0g sample
50 ml 0.3 mM NH_4PO_4
1x10^5 Escherichia coli / ml
0.01% QS-5211 wetting agent
1 hour contact time

ACTM 0208 BPB Direct Stain (Uniformity):
1.0g sample
0.036% BPB dH_2O solution
20 minute exposure

ACTM 0219 BPB Extraction (EXT):
1.0g sample
0.001% BPB dH_2O solution
20 minute exposure
594nm Absorbance
0.01% QS-5211 wetting agent

AATCC 61-1996 Accelerated Laundering (Washes)
Test 2A
49° ±3°C
50 Steel Balls
0.15% AATCC Standard Reference Detergent
ACTM 6001 Post Laundering Protocol

TABLE 3 (fungal test; Aspergillus niger ATCC 6275)

	Fungal rating after 4 weeks of incubation (0-4 scale)	
Untreated fabric sample	4	No antifungal activity

These data show that in each case, the untreated fabrics had no ability on their own to protect against bacteria or fungi, while the fabric treated in accordance with the present invention provided >99.99% reduction of bacterial presence, and maintained the effectiveness even through multiple accelerated wash/dry cycles under the AATCC 61-1996 Accelerated Laundering standard. Further, the present invention provided nearly complete protection against even MRSA (methicillin resistant staphylococcus aureus). The present invention also was shown to be effective against not only bacteria, but also against fungi.

One of ordinary skill would not expect to achieve such activity using the present invention antimicrobial agent under such mild treatment conditions. The above results are particularly surprising given the teaching of Smith III that such an antimicrobial agent requires much higher temperatures of drying in order to provide the treated article with antimicrobial properties.

4. The undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

5. Further deponent saith not.

Signature

1/11/08

Date

Customer Number
22850
Tel. (703) 413-3000
Fax. (703) 413-2220
(OSMMN 05/06)

LEXSEE 9 F3D 1531

IN RE ALBERT M.A. RIJCKAERT and JOANNES A.E. VAN DER KOP

93-1206

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

9 F.3d 1531; 1993 U.S. App. LEXIS 30162; 28 U.S.P.Q.2D (BNA) 1955

November 23, 1993, Decided

PRIOR HISTORY: [**1] Appealed from: U.S. Patents and Trademark Office Board of Patent Appeals and Interferences

DISPOSITION: REVERSED

COUNSEL: Edward W. Goodman, North American Philips Corporation, of Tarrytown, New York, argued for appellant. With him on the brief was Algy Tamoshunas.

Lee E. Barrett, Associate Solicitor, Office of the Solicitor, of Arlington, Virginia, argued for appellee. With him on the brief was Fred E. McKelvey, Solicitor.

JUDGES: Before MAYER and LOURIE, Circuit Judges, and LAY, * Senior Circuit Judge.

> * Honorable Donald P. Lay, Senior Circuit Judge, United States Court of Appeals for the Eighth Circuit, sitting by designation.

OPINION BY: LOURIE

OPINION

[*1531] LOURIE, *Circuit Judge.*

Albert Rijckaert and Joannes van der Kop ("Rijckaert") appeal from the decision of the United States Patent and Trademark Office (PTO), Board of Patent Appeals and Interferences affirming the final rejection of claims 5-12, all of the pending claims in patent application serial no. 07/345,396, as being unpatentable under *35 U.S.C. § 103 (1988).* Because the references relied upon to reject [*1532] the claims do not provide the basis for a *prima facie* determination that the claimed invention would have been obvious, [**2] we reverse.

BACKGROUND

The patent application at issue relates to an apparatus for recording and reproducing an electric signal on a magnetic record carrier. Independent claim 11 is drawn to a recording apparatus and it specifies a relationship between time expansion or compression and three variables a, n, and M. Claim 11 reads, in pertinent part:

> 11. An apparatus for recording an electric signal on a magnetic record carrier in tracks which are inclined relative to the longitudinal direction of said record carrier, comprising: . . .
>
> . . . .
>
> . . . [a] time-base correction circuit providing a time expansion or time compression of the signal blocks by a factor of a*n/(180*(M+1)), where a is the wrapping angle of the record carrier around the head drum and differs from 180 degrees, n is the number of head pairs, and M is the number of times within a specific time interval that a head pair which comes in contact with the record carrier during said time interval does not record a signal on the record carrier, said time interval being defined by those instants at which two consecutive track pairs are recorded by one or two head pairs.

Independent claim 12 is drawn to an apparatus [**3] for reproducing a recorded signal and it recites the reciprocal relationship between time compression or expansion and the three variables a, n, and M. Dependent claims 5-10 further limit claims 11 or 12.

The Board upheld the final rejection of claims 5 and 7-12 under *35 U.S.C. § 103* as being unpatentable over U.S. Patent 4,757,392 to Awamoto in view of Driessen et al., *An Experimental Digital Video Recording System,* CE-32 I.E.E.E. Transactions on Consumer Electronics 3, Aug. 1986, at 362-70. The Board also upheld the final rejection of claim 6 as being unpatentable over Awamoto and Driessen in view of U.S. Patent 4,542,417 to Ohta.

DISCUSSION

We review *de novo* the Board's ultimate determination of obviousness. *In re De Blauwe, 736 F.2d 699, 703, 222 USPQ 191, 195 (Fed. Cir. 1984).* Underlying factual inquiries, such as the scope and content of the prior art, differences between the prior art and the claimed invention, and level of ordinary skill in the art are reviewed for clear error. *See In re Caveney, 761 F.2d 671, 674, 226 USPQ 1, 3 (Fed. Cir. 1985).* [**4]

In rejecting claims under *35 U.S.C. § 103*, the examiner bears the initial burden of presenting a *prima facie* case of obviousness. *In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).* Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant. *Id.* "A *prima facie* case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art." *In re Bell, 991 F.2d 781, 782, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993)* (quoting *In re Rinehart, 531 F.2d 1048, 1051, 189 USPQ 143, 147 (CCPA 1976)).* If the examiner fails to establish a *prima facie* case, the rejection is improper and will be overturned. *In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).*

All of the claims except claim 6 stand rejected under *35 U.S.C. § 103* as being obvious [**5] over Awamoto in view of Driessen. [1] Awamoto, the primary reference, discloses a signal processing circuit for a video recording and reproducing apparatus. Awamoto specifically discloses the time expansion of an input signal by a factor of two and the corresponding time compression of an output signal in a manner inverse to that of the time expansion. Further, Awamoto uses two video heads mounted on a rotary drum "of any [*1533] of a well known video tape loading mechanism such that [the heads] follow parallel tracks skewed relative to the length of video tape." Driessen discloses a recording system using two pairs of heads mounted on piezoceramic actuators.

1 The claims stand or fall together since no separate argument for patentability has been made for each claim.

The Board concluded that the subject matter of the claims would have been obvious over Awamoto in view of Driessen, stating that "the time expansion or time compression relationship is satisfied for the expansion of two disclosed [in] Awamoto when a wrapping [**6] angle of 360 degrees, one pair of heads and no non-recording intervals are assumed." The Board further asserted that the recognition of the claimed relationship between time expansion/compression and the three variables a, n, and M is "the mere discovery of a relationship that is applicable to [a] prior art apparatus[, and] does not [give] rise to a patentable invention." Thus, in affirming the rejection, the Board first assumed that the claim limitation at issue, the relationship between time expansion/compression and the three variables, was somehow "inherent" in the prior art as shown by Awamoto. The Board also assumed specific values for the claimed variables in order to assert that Awamoto's device satisfies the claimed relationship.

Rijckaert argues that the examiner has not established a *prima facie* case of obviousness and that the examiner's assumptions do not constitute the disclosure of prior art. We agree. Awamoto does not disclose the wrapping angle of the record carrier around the head drum or the number of times that a head pair which comes in contact with the record carrier does not record a signal on the record carrier. Nor does Awamoto discuss the claimed relationship [**7] of the three variables to time expansion/compression. [2] Driessen, the secondary reference, is relied upon only to teach the provision of a pair of write heads having a mechanically rigid coupling to each other and does not remedy the deficiencies of Awamoto. Thus, the prior art relied upon does not disclose, suggest, or render obvious the claimed invention, either individually or when combined. [3]

2 The Commissioner admits that other limitations recited in claims 11 and 12 are not found in Awamoto; however, those limitations were not argued before the Board or this court. Thus, we agree with the Commissioner that those limitations are not at issue here.

3 The Board also noted that the claims are not "specific" in that they claim the three variables as a "factor" of the expansion or compression time. The Board stated, "claims 11 and 12 fail to say which of expansion time or compression time is factored by the variables, how or when one of the two times is selected based on the variables or how each of the two times is related to the vari-

ables." The Board further stated, "the relationship is probably satisfied by any prior art video tape recording and reproducing apparatus that otherwise satisfies the remaining requirements of the claims at bar." While the Board's position implies a possible rejection based upon *35 U.S.C. § 112*, this issue is not before us. In any event, the statement that the relationship is "probably satisfied" by the prior art is speculative and therefore does not establish a *prima facie* case of unpatentability.

[**8] Awamoto does not describe the use of time expansion and compression as a means of optimally filling tracks, much less suggest that the three variables of the claims are even a factor in determining the amount of time expansion or time compression. Rather, Awamoto is concerned primarily with processing a high-quality broadcast television signal for use in conventional video machinery, and with compensating for errors introduced to such a signal by a transfer circuit. The Commissioner's assertion "that the [analysis discussed in his brief] and Awamoto demonstrate that the relationship was, in fact, well known in the art" is unavailing. While the court appreciates the Commissioner's thorough explanation of the claimed relationship in his brief, the Commissioner's brief is not prior art. The prior art is Awamoto, and it does not indicate that the relationship is well known in the art, nor does it suggest the claimed relationship. *See In re Yates, 663 F.2d 1054, 211 USPQ 1149, 1151 (CCPA 1981)* (when the PTO asserts that there is an explicit or implicit teaching or suggestion in the prior art, it must indicate where such a teaching or suggestion [**9] appears in the reference).

To support the Board's affirmance of the rejection, the Commissioner points out that in the recording art, the exact matching of signal time to recording time is an optimal [*1534] condition, and that this condition would be met by fulfilling the claimed relationship. While the condition described may be an optimal one, it is not "inherent" in Awamoto. Nor are the means to achieve this optimal condition disclosed by Awamoto, explicitly or implicitly. "The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient [to establish inherency.]" *In re Oelrich, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981)* (citations omitted) (emphasis added). "That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown." *In re Spormann, 53 C.C.P.A. 1375, 363 F.2d 444, 448, 150 USPQ 449, 452 (CCPA 1966)*. Such a retrospective view of inherency is not a substitute for some teaching or suggestion supporting an obviousness rejection. *See In re Newell, 891 F.2d 899, 901, 13 USPQ2d 1248, 1250 (Fed. Cir. 1989)*. [**10]

Rijckaert also argues that the rejection of dependent claim 6 as being obvious over Awamoto and Driessen in view of Ohta is improper. Ohta discloses an apparatus for compensating for signal loss in a single-head video recorder using a time compression factor of 3/5 (a signal of time period 5t/4 is compressed into a track of time period 3t/4) so that a signal is recorded completely during the time period that it takes the recording head to scan the magnetic tape. Regarding the Ohta patent, the examiner stated, "Ohta was only relied upon to support the idea that other compression factors are used in the prior art . . . ." [4] The relationship between the time expansion/compression and the three variables recited in the claims from which claim 6 depends, which is absent in the combination of Awamoto and Driessen, is not supplied by Ohta. Thus, we agree that the rejection of claim 6 under *§ 103* is improper for the reasons set forth above with respect to the other claims.

4 The Board did not specifically address the rejection of claim 6; therefore, claim 6 was considered to be affirmed for the reasons stated by the examiner. *See* 37 C.F.R. § 1.196(a) (1993).

[**11] While the Commissioner criticizes Rijckaert's arguments regarding the *§ 103* rejections, the burden to rebut a rejection of obviousness does not arise until a *prima facie* case has been established. In the case before us, it was not.

CONCLUSION

The decision of the United States Patent and Trademark Office Board of Patent Appeals and Interferences affirming the final rejection is reversed.

REVERSED

LEXSEE 169 F3D 743

IN RE ANTHONY J. ROBERTSON and CHARLES L. SCRIPPS

98-1270

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

169 F.3d 743; *1999 U.S. App. LEXIS 3224*; *49 U.S.P.Q.2D (BNA) 1949*

February 25, 1999, Decided

PRIOR HISTORY: [**1] Appealed from: Patent and Trademark Office Board of Patent Appeals and Interferences. (Serial No. 08/171,484).

DISPOSITION: REVERSED.

COUNSEL: Kenneth R. Adamo, Jones, Day, Reavis & Pogue, of Cleveland, Ohio, argued for appellant. With him on the brief were Calvin P. Griffith, and Gregory A. Castanias, of Washington, DC. Of counsel on the brief was Steven W. Miller, The Proctor & Gamble Company, of Cincinnati, Ohio.

Linda Moncys Isacson, Associate Solicitor, Office of the Solicitor, of Arlington, Virginia, argued for appellee. With her on the brief were Albin F. Drost, Acting Solicitor, and John M. Whealan, Associate Solicitor.

JUDGES: Before NEWMAN, Circuit Judge, FRIEDMAN, Senior Circuit Judge, and RADER, Circuit Judge. Opinion for the court filed by Senior Circuit Judge FRIEDMAN, in which Circuit Judge NEWMAN joins. Concurring opinion filed by Circuit Judge RADER.

OPINION BY: FRIEDMAN

OPINION

[*744] FRIEDMAN, *Senior Circuit Judge*:

This appeal challenges the decision of the Board of Patent Appeals and Interferences (Board) that claim 76 in the appellants' patent application was anticipated by and obvious over United States Patent No. 4,895,569 (the Wilson patent). We reverse.

I

Both claim 76 and [**2] Wilson involve fastening and disposal systems for diapers. In both, the body of the diaper features a small front and a larger rear section. The outer edges of those sections are attached at the wearer's waist in the hip area. Once the diaper is soiled and then removed, the smaller front section is rolled up into the larger rear section and secured in this rolled-up configuration by fasteners.

The appellants' application is for "an improved mechanical fastening system for . . . disposable absorbent articles [*i.e.*, diapers] that provides convenient disposal of the absorbent article." Claim 76 covers:

> [A] mechanical fastening system for forming side closures . . . comprising
>
> a closure member . . . comprising a first mechanical fastening means for forming a closure, said first mechanical fastening means comprising a first fastening element;
>
> a landing member . . . comprising a second mechanical fastening means for forming a closure with said first mechanical fastening means, said second mechanical fastening means comprising a second fastening element mechanically engageable with said first element; and
>
> disposal means for allowing the absorbent article [**3] to be secured in a disposal configuration after use, said disposal means comprising a third mechanical fastening means for securing the absorbent article in the disposal configuration, said third mechanical fastening

> means comprising a third fastening element mechanically engageable with said first fastening element . . .

Claim 76 thus provides for two mechanical fastening means to attach the diaper to the wearer and a third such means for securing the diaper for disposal.

The Wilson patent discloses two snap elements on fastening strips attached to the outer edges of the front and rear hip sections of the garment. The fastening strips may also include "secondary load-bearing closure means" - additional fasteners to secure the garment; they may be identical to the snaps.

Wilson also states:

> Disposal of the soiled garment upon removal from the body is easily accomplished by folding the front panel . . . inwardly and then fastening the rear pair of mating fastener members . . . to one another, thus neatly bundling the garment into a closed compact package for disposal.

[*745] In other words, Wilson does not provide a separate fastening means to be used in disposing of the [**4] diaper. Instead, it suggests that disposal of the used diaper may be "easily accomplished" by rolling it up and employing the same fasteners used to attach the diaper to the wearer to form "a closed compact package for disposal."

In holding that the invention claim 76 covers was anticipated by Wilson, the Board did not hold that Wilson set forth a third fastening means. Instead, it found that Wilson anticipated claim 76 "under principles of inherency." Applying the language of claim 76 to the operation of Wilson, it concluded that "an artisan would readily understand the disposable absorbent garment of Wilson . . . as being inherently capable of [making the secondary load-bearing closure means] (third fastening element) mechanically engageable with [the other snap fasteners on the fastening strip] (first fastening element)" - *i.e.*, using the secondary closure not with its mate, but with one of the primary snap fasteners. The Board summarily affirmed the examiner's alternative ruling that claim 76 would have been obvious in light of Wilson because "claim 76 lacks novelty."

II

Anticipation under *35 U.S.C. § 102(e)* requires that "each and every element as set forth in the [**5] claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 U.S.P.Q.2D (BNA) 1051, 1053 (Fed. Cir. 1987).*

A. The Wilson patent does not expressly include a third fastening means for disposal of the diaper, as claim 76 requires. That means is separate from and in addition to the other mechanical fastening means and performs a different function than they do. Indeed, Wilson merely suggests that the diaper may be closed for disposal by using the same fastening means that are used for initially attaching the diaper to the body.

B. If the prior art reference does not expressly set forth a particular element of the claim, that reference still may anticipate if that element is "inherent" in its disclosure. To establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268, 20 U.S.P.Q.2D (BNA) 1746, 1749 (Fed. Cir. 1991).* "Inherency, however, may not be established by probabilities or [**6] possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Id. at 1269, 20 U.S.P.Q.2D (BNA) at 1749* (quoting *In re Oelrich, 666 F.2d 578, 581, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981).*

In finding anticipation by inherency, the Board ignored the foregoing critical principles. The Board made no attempt to show that the fastening mechanisms of Wilson that were used to attach the diaper to the wearer also "necessarily" disclosed the third separate fastening mechanism of claim 76 used to close the diaper for disposal, or that an artisan of ordinary skill would so recognize. It cited no extrinsic evidence so indicating.

Instead, the Board ruled that one of the fastening means for attaching the diaper to the wearer also could operate as a third fastening means to close the diaper for disposal and that Wilson therefore inherently contained all the elements of claim 76. In doing so, the Board failed to recognize that the third mechanical fastening means in claim 76, used to secure the diaper for disposal, was separate from and independent of the two other mechanical means used to attach the diaper to the person. The Board's theory that [**7] these two fastening devices in Wilson were capable of being intermingled to perform the same function as the third and first fastening elements in claim 76 is insufficient to show that the latter device was inherent in Wilson. Indeed, the Board's analysis rests upon the very kind of probability or possibility - the odd use of fasteners with other than their mates - that this court has pointed out is insufficient to establish inherency.

III

The Board's entire discussion of obviousness was as follows:

> [*746] ***The rejection of claim 76 under 35 USC § 103***
>
> We sustain the rejection of claim 76 under *35 USC § 103*.
>
> Above, we found that claim 76 lacks novelty. Lack of novelty is the ultimate of obviousness. See *In re Fracalossi, 681 F.2d 792, 794, 215 U.S.P.Q. (BNA) 569, 571 (CCPA 1982)*. Thus, claim 76 is appropriately rejected under *35 USC § 103* as being unpatentable.

The "lack of novelty" upon which the Board based its conclusion of obviousness, however, was its finding of anticipation. Our rejection of that finding eliminates the sole basis of the Board's obviousness determination, which therefore cannot stand. *See In re Adams, 53 C.C.P.A. 1433, 364 F.2d 473, 480, 150 U.S.P.Q. 646,* [**8] *651 (C.C.P.A. 1966)*.

In his brief the Commissioner argues:

> Moreover, even if this court interprets claim 76 to require two separate fasteners to perform the closure and disposal functions, it would have been well within the knowledge of one of ordinary skill in the art to take Wilson's one fastener and make it into two separate fasteners. *See* [*In re*] *Graves, 69 F.3d [1147,] 1152, 36 U.S.P.Q.2D (BNA) [1697,] 1701* [(Fed. Cir. 1995)] (When evaluating a reference, it is appropriate to consider the knowledge of a skilled artisan in combination with the teaching of the reference.). Accordingly, claim 76 would have been obvious to one of ordinary skill in the art, and the rejection should be affirmed by this Court.

That, of course, was not the ground on which the Board based its obviousness ruling. We decline to consider counsel's newly-minted theory as an alternative ground for upholding the agency's decision. *See In re Soni, 54 F.3d 746, 751, 34 U.S.P.Q.2D (BNA) 1684, 1688 (Fed. Cir. 1995)* (citing *In re DeBlauwe, 736 F.2d 699, 705 n.7, 222 U.S.P.Q. 191, 196 n.7 (Fed. Cir. 1984)*. The Board's obviousness ruling cannot be sustained on the ground the Board gave.

[**9] CONCLUSION

The decision of the Board of Patent Appeals and Interferences affirming the examiner's rejection of claim 76 as anticipated by and obvious over the Wilson patent is

REVERSED.

CONCUR BY: RADER

CONCUR

RADER, *Circuit Judge*, concurring.

Robertson asserts that the prior art Wilson patent does not teach three elements of claim 76: a "third mechanical fastening means," a disposal means on the "outside surface" of the body portion, and end regions that are "in an overlapping configuration when worn." In reversing the Board, this court relies solely on the purported failure of Wilson to teach the third fastening means. Because I believe Wilson teaches such a means, but does not teach the other two limitations at issue, I concur.

In its analysis, this court assumes without discussion that the claimed "third mechanical fastening means" covers a *separate* third mechanical fastening means. This issue is key, for if the claim does not require a separate third fastening means, but instead allows the first fastening means to also serve as the third, then the prior art Wilson patent clearly teaches that element of the claim. For two reasons, this claim does not, to my eyes, [**10] require a separate third fastening means. First, the claim does not specifically recite a *separate* third fastening means. Second, because the claim is in means-plus-function form, this court consults the specification to identify structure. The specification explicitly teaches that the first and third fastening elements can be the same so long as they are complementary, as they are in Wilson. Accordingly, I agree with the Board that Wilson teaches the claimed "third fastening element."

Wilson does not, however, teach either of the other two claim limitations at issue. As to the disposal means on the "outside surface" of the body portion, Wilson's figs. 12 and 13a-d show the disposal means on the inside of the body portion. As to the end regions that are "in an overlapping configuration when worn," Wilson explicitly teaches that the end regions should abut, not overlap, when worn. To overcome these teachings, the Board relied on the following statement in Wilson: "Further, the fastener members [*747] need not be previously mounted on a separate strip as shown then bonded . . . to the stretchable outer cover . . . . Multi-component snaps are available which may be applied directly to a [**11]

stretchable outer cover material . . . ." Col. 7, l. 65 to col. 8, l. 3. The Board opined that applying snaps directly to the outer cover would result in both a disposal means on the "outside surface" and end regions "in an overlapping configuration when worn." Simply put, the Board has put more weight on this teaching than it can bear. It is far from clear what effect applying the snaps directly to the outer cover will have on the Wilson diaper configuration, let alone that it will result in a configuration satisfying the claim elements at issue. Accordingly, because I believe that the Board clearly erred in this interpretation of Wilson, I would reverse on this ground.

LEXSEE 370 F3D 1354

METABOLITE LABORATORIES, INC. and COMPETITIVE TECHNOLOGIES, INC., Plaintiffs-Appellees, v. LABORATORY CORPORATION OF AMERICA HOLDINGS (doing business as LabCorp), Defendant-Appellant.

03-1120

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

370 F.3d 1354; 2004 U.S. App. LEXIS 11248; 71 U.S.P.Q.2D (BNA) 1081

June 8, 2004, Decided

SUBSEQUENT HISTORY: Rehearing denied by, Rehearing, en banc, denied by *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 2004 U.S. App. LEXIS 17408 (Fed. Cir., Aug. 5, 2004)*
Subsequent appeal at *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 121 Fed. Appx. 396, 2005 U.S. App. LEXIS 2739 (Fed. Cir., 2005)*
Later proceeding at *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 543 U.S. 1185, 125 S. Ct. 1413, 161 L. Ed. 2d 188, 2005 U.S. LEXIS 2077 (2005)*
US Supreme Court certiorari granted by, in part *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 546 U.S. 945, 546 U.S. 975, 126 S. Ct. 543, 163 L. Ed. 2d 458, 2005 U.S. LEXIS 7857 (2005)*
US Supreme Court certiorari granted by, in part, On reconsideration by *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 546 U.S. 999, 126 S. Ct. 601, 163 L. Ed. 2d 501, 2005 U.S. LEXIS 8202 (2005)*
US Supreme Court certiorari dismissed by *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 126 S. Ct. 2921, 165 L. Ed. 2d 399, 2006 U.S. LEXIS 4893 (2006)*
Motion denied by, Motion granted by, in part *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 2006 U.S. Dist. LEXIS 67901 (D. Colo., Sept. 20, 2006)*
Related proceeding at *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 2008 U.S. Dist. LEXIS 63213 (D. Colo., Aug. 15, 2008)*

PRIOR HISTORY: [**1] Appealed from: United States District Court for the District of Colorado. Senior Judge Zita L. Weinshienk.

DISPOSITION: Affirmed.

COUNSEL: Glenn K. Beaton, Gibson, Dunn & Crutcher LLP, of Denver, Colorado, argued for plaintiffs-appellees. With him on the brief were J. Gregory Whitehair and Amanda J. Tessar. Also on the brief was Mark A. Perry, of Washington, DC.

Jonathan S. Franklin, Hogan & Hartson L.L.P., of Washington, DC, argued for defendant-appellant. With him on the brief was Catherine E. Stetson. Of counsel on the brief was John P. Higgins, Alston & Bird, LLP, of Charlotte, North Carolina.

JUDGES: BEFORE RADER, Circuit Judge, FRIEDMAN, Senior Circuit Judge, and SCHALL, Circuit Judge. Opinion for the court filed by Circuit Judge RADER, dissenting-in-part and concurring-in-part opinion filed by Circuit Judge SCHALL.

OPINION BY: RADER

OPINION

[*1358] RADER, *Circuit Judge.*

In the United States District Court for the District of Colorado, a jury found that Laboratory Corporation (LabCorp) indirectly infringed Metabolite Laboratories, Inc.'s (Metabolite's) *U.S. Patent No. 4,940,658* (the '658 patent). The jury also found that LabCorp partially breached its contract with Metabolite. Based on this verdict, [**2] the district court assessed damages of $ 3,652,724.61 for breach of contract and $ 1,019,365.01 for indirect infringement. *Metabolite Labs., Inc. v. Lab.*

Corp., No. 99-Z-870 (D. Colo. Dec. 3, 2001). After denying LabCorp's motion for judgment as a matter of law (JMOL), the district court doubled the infringement award for willful infringement and issued a permanent injunction. *Metabolite Labs., Inc. v. Lab. Corp.*, No. 99-Z-870 (D. Colo. Nov. 19, 2001). Because the record supports the jury's verdicts and the trial court's decisions, this court affirms.

I.

The *'658 patent* claims methods for detecting cobalamin or folate deficiency. Cobalamin and folate are both B vitamins, commonly known as B[12] and folic acid, respectively. A deficiency in these vitamins can cause serious illnesses in humans, including vascular disease, cognitive dysfunction, birth defects and cancer. If detected early enough, however, vitamin supplements readily treat the deficiency.

Because these B vitamins assist in metabolizing the amino acid homocysteine, scientists directly assayed homocysteine to screen for cobalamin and folate deficiency. These direct homocysteine assays were unreliable. Then [**3] researchers at University Patents Inc. (UPI) discovered a relationship between elevated levels of total homocysteine and a deficiency in either cobalamin or folate. The total homocysteine test, however, could not alone identify which vitamin was deficient. Total homocysteine includes free and protein-complexed homocysteine and also includes homocysteine derivatives homocystine and homocysteine-cysteine.

Originally, doctors could not conveniently treat both deficiencies because while folate was available in tablet form, cobalamin could only be administered by injection. After cobalamin became available in tablet form, however, doctors could simply order a total homocysteine test and, without identifying the deficient vitamin, treat elevated levels of total homocysteine with a tablet containing both cobalamin and folate. The UPI inventors also developed a test to identify the deficient vitamin using methylmalonic acid (the panel test method). The *'658 patent* claims both the total homocysteine test and the total homocysteine-methylmalonic acid test.

Claim 13 claims the total homocysteine test:

> 13. A method for detecting a deficiency of cobalamin or folate in warm-blooded animals [**4] comprising the steps of:
>
> assaying a body fluid for an elevated level of total homocysteine; and
>
> [*1359] correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.

'658 patent, col. 11, ll. 58-65.

UPI's successor, Competitive Technologies Inc., licensed the patent to Metabolite, which in turn sublicensed the patent to Roche Biomedical Laboratories (now LabCorp). LabCorp, a laboratory testing company, originally performed total homocysteine assays under the sublicense. But in 1998, LabCorp switched to a total homocysteine assay developed by Abbott Laboratories (Abbott test) and discontinued royalty payments to Metabolite for total homocysteine assays.

In response, Metabolite sued LabCorp for infringement. The district court construed the disputed claim terms, and the case proceeded to a jury. The jury found that LabCorp breached its license agreement with Metabolite, that LabCorp willfully infringed the *'658 patent*, and that the claims at issue are not invalid. The jury assessed damages against LabCorp of $ 3,652,724.61 for breach of contract and $ 1,019,365.01 for infringement. The district court entered judgment [**5] against LabCorp and awarded damages as assessed by the jury.

After the trial, the district court denied LabCorp's motion for JMOL on infringement, breach of contract, invalidity, and willful infringement. In light of the finding of willfulness, the district court doubled the jury's infringement award to $ 2,038,730.02. The district court also permanently enjoined LabCorp from using the homocysteine-only test. LabCorp appeals the district court's claim construction as well as the denial of JMOL.

II.

Claim construction is a matter of law that this court reviews without deference. *Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998)* (en banc). The jury's finding of infringement, however, raises questions of fact, which this court reviews for substantial evidence. *Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343, 1348-49 (Fed. Cir. 2000).*

This court reviews a denial of JMOL without deference by reapplying the JMOL standard. Thus, this court will affirm a denial of JMOL unless substantial evidence does not support the jury's factual findings or the verdict rests on legal errors. *Waner v. Ford Motor Co., 331 F.3d 851, 855 (Fed. Cir. 2003).* [**6]

Whether a specification complies with the written description requirement of *35 U.S.C. § 112, paragraph 1*, is a question of fact that this court reviews for substantial evidence. *Union Oil v. Atl. Richfield Co., 208 F.3d 989, 996 (Fed. Cir. 2000)*. Enablement is a matter of law that this court reviews without deference; however, this court reviews the factual underpinnings of enablement for substantial evidence. *BJ Servs. Co. v. Halliburton Energy Servs., Inc., 338 F.3d 1368, 1371-72 (Fed. Cir. 2003)*. Similarly, this court reviews the legal determination of obviousness without deference, but reviews its factual underpinnings for substantial evidence. *Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1323 (Fed. Cir. 2002)*. This court reviews a legal finding of indefiniteness without deference. *BJ Servs., 338 F.3d at 1371-72*. Whether a prior art reference anticipates a patent is a factual determination that this court reviews for substantial evidence. *Teleflex, 299 F.3d at 1323*.

Whether infringement was willful is a question of fact that this court reviews for substantial [**7] evidence. *Crystal Semiconductor Corp. v. TriTech Microelecs. Int'l, Inc., 246 F.3d 1336, 1346 (Fed. Cir.* [*1360] *2001)*. This court reviews an award of enhanced damages and grant of a permanent injunction for abuse of discretion. *Odetics, Inc. v. Storage Tech. Corp., 185 F.3d 1259, 1272 (Fed. Cir. 1999)*.

III.

Infringement

The primary challenge to the jury's indirect infringement verdict requires this court to review the district court's construction of the claim term "correlating." The infringement inquiry is a two-step process. This court construes the disputed claim terms and then compares the properly construed claims to the accused device. *Cybor Corp., 138 F.3d at 1454*. Thus, this court first reviews the district court's claim construction.

As always, the claim language itself governs its meaning. *Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)*. This court construes the meaning of claim language according to its usage and context. *ResQNet.com, Inc. v. Lansa, Inc., 346 F.3d 1374, 1378 (Fed. Cir. 2003)*. The touchstone for discerning the usage of claim language is the understanding [**8] of those terms among artisans of ordinary skill in the relevant art at the time of invention. *See Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342 (Fed. Cir. 2001)*. Indeed, normal rules of usage create a "heavy presumption" that claim terms carry their accustomed meaning in the relevant community at the relevant time. *CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002)* (citing *Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed. Cir. 1999))*. Thus, this court sets the meaning of claim terms by ascertaining their technological and temporal context.

In most cases, the best source for discerning the proper context of claim terms is the patent specification wherein the patent applicant describes the invention. In addition to providing contemporaneous technological context for defining claim terms, the patent applicant may also define a claim term in the specification "in a manner inconsistent with its ordinary meaning." *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp., 320 F.3d 1339, 1347 (Fed. Cir. 2003)* (citing *Teleflex, 299 F.3d at 1325-26*). [**9] In other words, a patent applicant may define a term differently from its general usage in the relevant community, and thus expand or limit the scope of the term in the context of the patent claims. *Id.* Therefore, the primary aids to supply the context for interpretation of disputed claim terms are in the intrinsic record. *Vitronics, 90 F.3d at 1582 (Fed. Cir. 1996)*.

Another tool to supply proper context for claim construction is the prosecution history. As in the case of the specification, the patent applicant's consistent usage of a term in prosecuting the patent may enlighten the meaning of that term. *Middleton, Inc. v. Minn. Mining & Mfg. Co., 311 F.3d 1384, 1388 (Fed. Cir. 2002)* (a patent applicant may "clearly and unambiguously" disavow claim scope during prosecution).

This court also acknowledges the relevance of extrinsic evidence, often presented in the form of expert testimony. *Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1309 (Fed. Cir. 1999)* ("Consultation of extrinsic evidence is particularly appropriate to ensure that [the court's] understanding of the technical aspects of the patent is not entirely [**10] at variance with the understanding of one skilled in the art."); *Vitronics, 90 F.3d at 1585*. Another excellent source of context for disputed terms is dictionary definitions and treatises. *See, e.g., Tex. Digital Sys.,* [*1361] *Inc. v. Telegenix, Inc., 308 F.3d 1193, 1202 (Fed. Cir. 2002)* ("Dictionaries, encyclopedias and treatises are particularly useful resources to assist the court in determining the ordinary and customary meanings of claim terms.").

As noted before, these claim construction aids inform the court's task of ascertaining the meaning of the claim terms to one of ordinary skill in the art at the time of invention. *Moba v. Diamond Automation, Inc., 325 F.3d 1306, 1315 (Fed. Cir. 2003)* ("Moreover, as this court has repeatedly counseled, the best indicator of claim meaning is its usage in context as understood by one of skill in the art at the time of invention."); *Ferguson Beauregard v. Mega Sys., LLC, 350 F.3d 1327, 1338 (Fed. Cir. 2003)* ("The words used in the claims must be considered in context and are examined through the

viewing glass of a person skilled in the art."); *Interactive Gift Express, Inc. v. Compuserve Inc., 256 F.3d 1323, 1332 (Fed. Cir. 2001)* [**11] ("It is important to bear in mind that the viewing glass through which the claims are construed is that of a person skilled in the art."); *Markman v. Westview Instruments, Inc., 52 F.3d 967, 986 (Fed. Cir. 1995)* (en banc) ("The focus is on the objective test of what one of ordinary skill in the art at the time of the invention would have understood the term to mean."). In this case, as evidenced by the jury instruction, the parties agreed that the level of ordinary skill in this field of invention was "a person having a medical degree and experience in researching the amino acid homocysteine and its relationship to diseases."

The disputed term "correlating" appears in the second step of claim 13, which states: "Correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate." In its *Markman* brief below, LabCorp urged the district court to construe "correlate" according to its dictionary definition as a verb meaning "to establish a mutual or reciprocal relation of" an elevated level of homocysteine. LabCorp further argued that the district court should construe the "correlating" step as establishing that an elevated [**12] level of homocysteine is caused by a "shortage of cobalamin which causes a hematologic or neuropyschiatric abnormality," or "[a] deficiency of folate which causes a hematologic abnormality." The district court adopted LabCorp's dictionary definition by construing "correlating" to mean "to establish a mutual or reciprocal relationship between," but declined to "include a reference to hematologic or neuropsychiatric abnormality" in order to avoid impermissibly importing a limitation from the specification.

On appeal, LabCorp argues that claim 13's correlating step should be construed as establishing that an elevated level of homocysteine is caused by a "shortage of cobalamin which causes a hematologic or neuropsychiatric abnormality," or a "deficiency of folate which causes a hematologic abnormality." LabCorp interprets the specification to clearly define a "deficiency of cobalamin" as the presence of a clinical or hematologic syndrome or both that responds to cyano-cobalamin treatment, and to acknowledge that some clinical or hematologic syndrome or neuropsychiatric abnormality must be present. Thus, LabCorp contends that the correlation step of claim 13 should be construed to require [**13] a showing of a separate hematologic or neuropsychiatric symptom to confirm the "correlation."

The claim states that the method must correlate "an elevated level of total homocysteine . . . with a deficiency of cobalamin or folate." This language does not require a further association between the level of [*1362] total homocysteine and either a hematologic or neuropyschiatric abnormality or both. The claim only requires association of homocysteine levels with vitamin deficiencies. It requires no further correlation to confirm the relationship to vitamin deficiencies. The claim simply says nothing about a confirmatory step or a further correlation beyond the stated relationship.

The preamble further supports the district court's reading of the claim: "A method for detecting a deficiency of cobalamin or folate in warm-blooded animals." This language restates that the invention detects vitamin deficiency. This introductory language does not relate those deficiencies to any particular abnormality. A preamble may provide context for claim construction, particularly, where as here, that preamble's statement of intended use forms the basis for distinguishing the prior art in the patent's prosecution [**14] history. *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 809 (Fed. Cir. 2002)* (in rare circumstances, a preamble's recitation of intended use may serve to distinguish the prior art).

An examination of the prosecution history of this patent brings the meaning of the preamble into focus. As originally filed, claim 13 did not contain the "correlating" step. The examiner rejected claim 13 under *35 U.S.C. § 112* because it did not "recite discrete, sequential process steps, for example, obtaining a sample, contacting the sample with, etc. The final step should be clearly related to the preamble of the claim." Rather than add a second step as the examiner suggested, however, the applicant responded: "As applicants are the first to detect cobalamin or folate deficiency by assaying body fluids for total homocysteine, it is believed that they are entitled to a claim of equivalent scope, not limited to any particular steps or methods." After this response, the examiner dropped the *§ 112* objection, but rejected claim 13 under *§ 102*: "In the absence of a correlation step, the preamble of claim 13 merely recites an intended use of the [**15] invention. The claim lacks a positive limitation for correlating to a particular condition and has only one method step recited." At that point, the applicant added the recommended "correlating" step. The examiner then allowed claim 13.

This prosecution history ties the preamble directly to the "correlating" step. Specifically, the recitation of the intended use in the preamble makes this invention a method for detecting a vitamin deficiency. "Detecting" in the medical context requires evaluation of all test results, both positive and negative, to evaluate a patient's condition. For example, the results of a pregnancy test can either be positive or negative. Either result is informative to the patient. Similarly, in this case, the assaying step can identify an elevated or an unelevated level of total homocysteine. Then the "correlating" step can identify, in cases of elevated levels, a relationship or not to vita-

min deficiency. The results in either the assaying or correlating steps are informative. Thus, the preamble supports the district court's construction that "correlating" includes ascertaining either a mutual or reciprocal relationship between total homocysteine and a vitamin [**16] deficiency. The preamble does not require this invention to show a further association with an abnormality.

The specification confirms that the claim language does not require as part of the method a confirmation that the elevated level causes some deleterious symptoms or abnormalities. LabCorp points to portions of the specification that discuss the relationship between the elevated levels and either clinical or hematologic symptoms. *See, e.g., '658 patent*, col. 10, ll. 56-61; col. 12, ll. 8-15. LabCorp would expand those [*1363] references to require some confirmatory step in the claim. The specification, however, does not require such a confirmatory step. Rather, the specification at one juncture acknowledges that the method can show vitamin deficiency without any clinical symptoms: "These findings led us to conclude that large numbers of patients with cobalamin deficiency lack the 'typical' clinical and hematologic features usually expected to be present in cobalamin deficiency . . . ." *Id.* at col. 11, ll. 40-45. In other words, the specification shows that the method can show an association between elevated levels and vitamin deficiency without any further clinical symptoms. [**17] Thus, the district court properly refused to import into the claims LabCorp's proposed limitation from the specification. The specification itself does not support such a limitation on the meaning of the claims.

As noted earlier, the district court construed "correlating" to mean a "mutual or reciprocal relationship between" the elevated levels and the vitamin deficiencies. The inventors discovered that assaying total homocysteine correlated with (or predicted relatively accurately) whether a patient had a deficiency of cobalamin or folate. *Id.* at col. 4. ll. 17-23; col. 10, ll. 35-42. The specification explains that an elevated level of total homocysteine often indicates a deficiency, while a non-elevated level indicates no deficiency. For example, the overview of the invention notes: "This invention pertains to . . . methods for determining whether said warm-blooded animal has a cobalamin deficiency, a folic acid deficiency, *neither*, or both." *Id.* at col. 1, ll. 13-15 (emphasis added). Next, in the summary of the invention, the patentee stated: "Accordingly, assays for homocysteine can be used to determine the *presence or absence* of cobalamin and/or folic acid deficiency [**18] in warm-blooded animals." *Id.* at col. 5, l. 66 - col. 6, l. 1 (emphasis added). This court observes that the perfect symmetry between "mutual or reciprocal" and "presence or absence" shows that the district court correctly placed the term "correlating" in its proper context with its proper meaning.

Finally, the patentee explained:

> Once folate and/or cobalamin deficiency has been determined, the progress of treatment can be monitored by repeating the assays periodically during and after treatment. A drop in the level of homocysteine in the serum and/or urine after oral or parenteral adminstration of cobalamin and/or folate as the case may be confirms the diagnosis.

Id. at col. 10, ll. 18-24. This recitation confirms that the patentee anticipated assays without an elevated level of total homocysteine, i.e., the reciprocal relationship, would further confirm the diagnosis by showing an improvement trend after a physician prescribed treatment.

Taken in the context of the entire specification, "correlating" means relating total homocysteine levels to cobalamin or folate deficiency, a deficiency in both, or a deficiency in neither. In essence, "correlating" means [**19] to relate the presence of an elevated total homocysteine level to either a cobalamin or folate deficiency, or both (i.e., a mutual relationship), and also to relate the absence of an elevated total homocysteine level to a deficiency in neither (i.e., a reciprocal relationship). The claim, in other words, provides that if the assay discloses "an elevated level of total homocysteine," the physician determines whether there is a cobalamin or folate deficiency by "correlating," i.e., comparing the elevated level with the normal homocysteine level. In sum, the specification and prosecution history confirm that the claim language "correlating," in the understanding of one of ordinary skill in this art field [*1364] at the time of invention, includes both a mutual relationship between the presence of an elevated level of homocysteine and a vitamin deficiency and a reciprocal relationship between the absence of an elevated level of homocysteine and no vitamin deficiency. Further, the claim language does not require a confirmatory step linking these conditions to diagnosed or apparent symptoms. The district court correctly construed the claim.

LabCorp also raises claim construction arguments in its [**20] challenge to the trial court's assessment of damages. Specifically, LabCorp contends that only twenty percent of the assays have elevated levels of homocysteine and therefore only this percentage could form the basis for a damages award. As noted earlier, LabCorp itself urged the district court to define "correlating" to include either a mutual or a reciprocal relationship. In the damages calculation, however, LabCorp pre-

fers to restrict the claim to correlations that yield mutual relationships while excluding any reciprocal relationships. This court declines the invitation to apply a different claim construction for computation of damages than for infringement liability.

As explained above, the mutual relationship is established when an elevated homocysteine level is present, whereas a reciprocal relationship is established when an elevated homocysteine level is absent. LabCorp's new damages argument, in essence, attempts to change its claim construction position to read out the reciprocal relationship that it initially urged. This court, as it does now, has previously declined such invitations. *Interactive Gift Express, 256 F.3d at 1346 (Fed. Cir. 2001)* ("[A] [**21] party will be judicially estopped from asserting a position on appeal that is inconsistent with a position it advocated at trial and persuaded the trial court to adopt."). For all purposes in this litigation, this court affirms the district court's construction of the "correlating" step.

Direct Infringement

The jury found LabCorp liable for indirect infringement. The record must show the presence of direct infringement, however, to support the verdict of indirect infringement. *Joy Techs., Inc. v. Flakt, Inc., 6 F.3d 770, 774 (Fed. Cir. 1993)* ("Liability for either active inducement of infringement or for contributory infringement is dependent upon the existence of direct infringement."). Thus, this court must examine whether there is substantial evidence in the record of the physicians' direct infringement. In that respect, the parties hinge the direct infringement issue solely on whether the physicians perform the correlating step. [1] Hence, we review the record for substantial evidence of that step.

1 This court, therefore, does not address the assaying step.

[**22] Substantial evidence supports the jury's verdict. The record shows that physicians order assays and correlate the results of those assays, thereby directly infringing. LabCorp's Discipline Director, Dr. Peter Wentz, testified that the physicians receiving total homocysteine assays from LabCorp carry out the correlating step. [2] Specifically, Dr. Wentz testified that "the correlating step . . . [is] a separate, distinct step that's performed by the physician who receives . . . our results." Inventor Dr. Sally Stabler also testified that it would be malpractice for a doctor to receive a total homocysteine assay without determining cobalamin/folate deficiency.

2 Peter Wentz has a doctoral, not a medical, degree.

To support the verdict, the record does not need to contain direct evidence that every physician performed the "correlating" [*1365] step. "It is hornbook law that direct evidence of a fact is not necessary. 'Circumstantial evidence is not only sufficient, but may also be more certain, satisfying and persuasive [**23] than direct evidence.'" *Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 1272 (Fed. Cir. 1986)* (citing *Michalic v. Cleveland Tankers, Inc., 364 U.S. 325, 330, 5 L. Ed. 2d 20, 81 S. Ct. 6 (1960))*. As discussed above, the record contains sufficient circumstantial evidence to permit the jury to imply that physicians directly infringe.

Active Inducement

Section 271(b) of title 35 provides: "Whoever actively induces infringement of a patent shall be liable as an infringer." *35 U.S.C. § 271(b) (2000)*. Although not express in the statute, this section requires proof of intent to induce infringement. *See, e.g., Hewlett Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469 (Fed. Cir. 1990)* ("proof of actual intent to cause the acts which constitute the infringement is a necessary prerequisite to finding active inducement"). A patentee may prove such intent through circumstantial evidence, much like direct infringement as discussed above. *See Water Techs. v. Calco, Ltd., 850 F.2d 660, 668 (Fed. Cir. 1988)* (noting that "circumstantial evidence may suffice" in proving intent).

The record contains such [**24] evidence of intent. LabCorp's own publications supply much of this evidence. LabCorp publishes both Continuing Medical Education articles as well as a Directory of Services that are specifically targeted to the medical doctors ordering the LabCorp assays. These publications state that elevated total homocysteine correlates to cobalamin/folate deficiency and that this deficiency can be treated with vitamin supplements. LabCorp's articles thus promote total homocysteine assays for detecting cobalamin/folate deficiency.

Faced with these statements, LabCorp attempts to explain that these articles focus on heart disease rather than vitamin deficiency. As noted earlier, the patent does not require a correlation to some particular medical condition, but to a vitamin deficiency. The publications advocate use of the assay to identify a need for cobalamin/folate supplements. Thus, the vitamin deficiency remains the focus of the assay and the treatment (i.e., vitamin supplements).

Accordingly, a reasonable jury could find intent to induce infringement because LabCorp's articles state that elevated total homocysteine correlates to cobalamin/folate deficiency. Moreover, the publications recommend [**25] treatment of this deficiency with vita-

min supplements. Because "intent is a factual determination particularly within the province of the trier of fact," *Allen Organ Co. v. Kimball Int'l, Inc., 839 F.2d 1556, 1557 (Fed. Cir. 1988)*, this court sees no reason to disturb the jury's finding regarding LabCorp's intent. Therefore, this court affirms the finding of indirect infringement based on the inducement analysis. This court declines to consider contributory infringement.

Invalidity

A patent issued from the United States Patent and Trademark Office (PTO) bears the presumption of validity under *35 U.S.C. § 282*. An accused infringer, therefore, must prove patent invalidity under the clear and convincing evidentiary standard. *Advanced Display Sys., Inc. v. Kent State Univ., 212 F.3d 1272 (Fed. Cir. 2000)*. LabCorp argues that claim 13 is invalid on grounds of indefiniteness, lack of written description and enablement, anticipation, and obviousness. Likewise, LabCorp contends that claim 18, directed to the panel test, is also invalid on grounds of [*1366] indefiniteness, and lack of written description and enablement.

Claim 13

First, [**26] LabCorp contends that the "correlating" step in claim 13 is indefinite. *35 U.S.C. § 112*, second paragraph, provides: "The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." *35 U.S.C. § 112, P 2 (2000)*. The requirement to "distinctly" claim means that the claim must have a meaning discernible to one of ordinary skill in the art when construed according to correct principles. *Union Pac. Res. Co. v. Chesapeake Energy Corp., 236 F.3d 684, 692 (Fed. Cir. 2001)*; *Rosemount, Inc. v. Beckman Instruments, Inc., 727 F.2d 1540, 1547 (Fed. Cir. 1984)*. Only when a claim remains insolubly ambiguous without a discernible meaning after all reasonable attempts at construction must a court declare it indefinite. *Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1375 (Fed. Cir. 2001)*. In this case, as already noted, the claim construction exercise at the trial court produced a discernible and clear meaning. No "material ambiguities" cloud the meaning of "correlating" to the extent [**27] that one of skill in the art would find the claim wholly indefinite. *All Dental Prodx, LLC v. Advantage Dental Prods., Inc., 309 F.3d 774, 780 (Fed. Cir. 2002)* ("Only after a thorough attempt to understand the meaning of a claim has failed to resolve material ambiguities can one conclude that the claim is invalid for indefiniteness."). This court affirms the trial court's denial of JMOL on this ground.

LabCorp next argues that the specification does not adequately describe the claimed invention under *35 U.S.C. § 112*, first paragraph:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains or with which it is most nearly connected, to make and use the same . . . .

35 U.S.C. § 112, P 1. This language contains both the written description and enablement tests for sufficiency of the specification's disclosure.

With regard to the written description test, this court has previously explained, "the test for compliance with *§ 112* has [**28] always required sufficient information in the original disclosure to show that the inventor possessed the invention at the time of the original filing." *Moba, 325 F.3d at 1320* (citing *Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1561 (Fed. Cir. 1991))*. As in the claim construction section above, this court assesses the written description possession test "from the viewpoint of one of skill in the art." *Moba, 325 F.3d at 1321*. The record is replete with evidentiary support that physicians in homocysteine research, i.e., persons of ordinary skill in the art, understood from the specification that the *'658 patent* inventors possessed the "correlating" step at the time they filed the patent application. For example, the examiner suggested the word "correlating" to the '658 patentee, showing that the PTO read the specification to include that feature. Additionally, the record reflects that LabCorp's own expert and employees understood the meaning of "correlating." Accordingly, this court finds that substantial evidence supports the jury finding that claim 13 was adequately supported by the *'658 patent*'s written description.

The specification [**29] also shows that the patentee enabled the claimed invention. In *Union Pacific*, this court held [*1367] that a claim was not enabled because it did not disclose use of a "comparing" step. *236 F.3d at 691*. However, in *Union Pacific*, the inventors "purposely excluded computer programming details" necessary to perform the "comparing" step. *Id. at 690*. In this case, the correlating step does not require computer technology or extensive computations. Instead, the record shows repeatedly that the correlating step is well within the knowledge of one of skill in this art. The correlating step is a simple conclusion that a cobalamin/folate deficiency exists *vel non* based on the assaying step. The patentee did not conceal or fail to disclose

this correlation, but instead featured it as the centerpiece of the invention. *See, e.g., '658 patent*, col. 4, ll. 17-20 ("It has now been discovered that an elevated level of total homocysteine in tissues of warmblooded [sic] animals correlates both with cobalamin deficiency and with folic acid deficiency . . . ."); *id.* at col. 5, ll. 64-66 ("It has been discovered that elevated levels of homocysteine in body tissue [**30] correlate with decreased levels of cobalamin and/or folic acid in said body tissue."); *id.* at col. 9, ll. 26-29 ("Homocysteine levels above these [previously specified] ranges are indicative of cobalamin and/or folate deficiency; the higher the level, the stronger the indication.").

The prior art reference (Refsum) does not anticipate claim 13 under *35 U.S.C. § 102*. "A prior art reference anticipates a patent claim if the reference discloses, either expressly or inherently, all of the limitations of the claim." *EMI Group N. Am., Inc. v. Cypress Semiconductor Corp., 268 F.3d 1342, 1350 (Fed. Cir. 2001)* (citation omitted). At the outset, the Refsum article does not recite all of the claim 13 limitations. Thus, anticipation would have to rely on an inherent disclosure of undisclosed features, in this case, the "correlating" limitation.

> To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, [**31] and that it would be so recognized by persons of ordinary skill.

Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991).

Refsum does disclose that total homocysteine should be used to investigate "perturbations of homocysteine metabolism in humans during disease or pharmacological interventions that affect metabolism of one-carbon compounds." Refsum, however, does not specifically mention cobalamin or folate deficiencies. Indeed, one of the *'658 patent* inventors, Dr. Stabler, testified that cobalamin and folate deficiencies constitute just such a perturbation that Refsum suggested warranted further investigation. Rather than necessarily containing the correlation between homocysteine and cobalamin or folate deficiencies, Refsum simply invites further experimentation to find such associations. An invitation to investigate is not an inherent disclosure. Construed most favorably for LabCorp, Refsum discloses no more than a broad genus of potential applications of its discoveries. A prior art reference that discloses a genus still does not inherently disclose all species within that broad category. *See Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1262 (Fed. Cir. 1989)* [**32] ("Under [defendant's] theory, a claim to a genus would inherently disclose all species. We find [this] argument wholly meritless . . . .").

Moreover, the PTO considered Refsum in allowing the claims. The *'658 patent* itself discusses Refsum at length at column 6, lines 26-43 and the patent's [*1368] second page cites Refsum as a reference. Where, as here, the PTO previously considered the prior art reference, LabCorp bears an even heavier burden to prove invalidity. *Hewlett-Packard, 909 F.2d at 1467.* ("This burden is especially difficult when the prior art was before the PTO examiner during prosecution of the application." (citation omitted)). Accordingly, substantial evidence supports the jury's finding that Refsum does not anticipate claim 13 by inherency.

The test of obviousness in *35 U.S.C. § 103* is the primary condition of patentability. Obviousness hinges on four factual findings: "(1) the scope and content of the prior art; (2) the differences between the prior art and the claims; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness." *Nat'l Steel Car, Ltd., v. Can. Pac. Ry., Ltd., 357 F.3d 1319, 1334 (Fed. Cir. 2004).* [**33] LabCorp posits that claim 13 is obvious in view of the Refsum article when combined with other references disclosing that partial homocysteine assays could help diagnose cobalamin or folate deficiency. First, as noted above in the anticipation analysis, the examiner considered the Refsum article and also considered all but one of the secondary references that LabCorp contends render the invention obvious in combination with Refsum. The one reference that the examiner did not consider is cumulative of the others. Thus, the heavy burden of proof in the anticipation case also applies to obviousness. *Hewlett-Packard, 909 F.2d at 1467.* Next, the secondary references do not refer to total homocysteine, but rather to homocystine, one of the four components of total homocysteine. Thus, these secondary references do not add considerably to the Refsum disclosure. Finally, even if the secondary references disclosed total homocysteine, the record does not contain evidence showing that one of skill in the art would have been motivated to combine the various references. *Ecolochem, Inc. v. S. Cal. Edison Co., 227 F.3d 1361, 1372 (Fed. Cir. 2000)* ("Obviousness cannot [**34] be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." (quoting *ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577 (Fed. Cir. 1984))).* These points alone would suffice to support the jury verdict.

Beyond these points, however, the record contains evidence of objective indicia that support the jury's nonobviousness verdict. The record, for example, shows that skilled artisans were initially skeptical about the invention. *See Hughes Tool Co. v. Dresser Indus., Inc., 816 F.2d 1549, 1556 (Fed. Cir. 1987)* (initial skepticism of experts is relevant to nonobviousness). The record also shows that Metabolite has licensed the invention to eight companies. *In re Sernaker, 702 F.2d 989, 996 (Fed. Cir. 1983)* (extensive licensing supports nonobviousness). Substantial evidence, therefore, supports the implied jury factual findings that support its legal conclusion that claim 13 is not obvious in light of the Refsum article and the cited secondary references.

In sum, this court rejects LabCorp's various attempts to invalidate claim 13. [**35] Accordingly, this court affirms the district court's denial of LabCorp's JMOL.

Claim 18

Unlike claim 13, which Metabolite specifically asserted in its motion for partial summary judgment, Metabolite also requested the district court to declare that claim 18 covers the panel test method. Specifically, Metabolite sought a declaration that LabCorp's panel test that determines which particular vitamin is deficient infringes claim 18. The district court [*1369] granted Metabolite's motion for partial summary judgment, finding that "claim 18 covers LabCorp's performance of the panel test." In turn, LabCorp challenged the validity of claim 18 at trial. Neither party disputes that LabCorp continues to pay royalties for the panel test that provides the capability to identify which of the two vitamins is deficient.

Before this court can reach the merits of LabCorp's validity challenge, however, it must first ascertain whether it has jurisdiction to consider this challenge. Subject matter jurisdiction is an inquiry that this court must raise *sua sponte*, even where, as here, neither party has raised this issue. *Textile Prods., Inc., v. Mead Corp., 134 F.3d 1481, 1485 (Fed. Cir. 1998)* [**36] ("Every federal appellate court has a special obligation to 'satisfy itself not only of its own jurisdiction, but also that of the lower courts in a cause under review,' even though the parties are prepared to concede it." (quotation omitted)); *see also Gen-Probe Inc. v. Vysis, Inc., 359 F.3d 1376, 1379 (Fed. Cir. 2004)* ("Any party or this court *sua sponte* may raise the question of subject matter jurisdiction.").

Although not as common as the scenario in which the alleged infringer seeks declaratory judgment against the patentee, it is possible for a patentee to also seek a declaratory judgment against a future infringer. *See Lang v. Pac. Marine & Supply Co., LTD., 895 F.2d 761, 763 (Fed. Cir. 1990)* (noting that patentees seeking declaratory judgments against future infringers are rare, yet permissible). In order to demonstrate that an actual case or controversy exists, however, a patentee must demonstrate two elements. First, the patentee must show that the future infringer is "engaged in an activity directed to making, selling, or using subject to an infringement charge under *35 U.S.C. § 271(a)*." *Lang, 895 F.2d at 764.* [**37] The patentee must then demonstrate that the defendant's acts represent a refusal to alter its course of action in light of the patentee's warning actions. *Id.*

The facts of this case, however, demonstrate that there is no real case or controversy regarding the LabCorp panel test, alleged to infringe claim 18. Neither party disputes that the license is still in effect as to the panel tests that LabCorp performs. This license is, in essence, a licensor's covenant not to sue the licensee. *Hilgraeve Corp. v. Symantec Corp., 265 F.3d 1336, 1346 (Fed. Cir. 2001)* (citation omitted). In turn, this court has held that a covenant not to sue deprives a court of declaratory judgment jurisdiction. *Amana Refrigeration, Inc. v. Quadlux, Inc., 172 F.3d 852, 855 (Fed. Cir. 1999)* (citing *Super Sack Mfg. Corp. v. Chase Packaging Corp., 57 F.3d 1054, 1060 (Fed. Cir. 1995)).* Accordingly, a licensor who has implicitly covenanted not to sue a licensee by virtue of the license agreement itself cannot seek a declaratory judgment of infringement. Moreover, in light of LabCorp's continuing royalty payments on the panel test, LabCorp cannot itself challenge [**38] the validity of a claim for which it continues to pay royalties. *Cf. Gen-Probe Inc., 359 F.3d at 1382* (holding that a licensee who continued paying royalties to the licensor did not have sufficient apprehension of suit giving rise to declaratory judgment subject matter jurisdiction). The district court's opinion concerning the panel test's infringement of claim 18 was merely advisory. Accordingly, the district court lacked subject matter jurisdiction, and this court vacates that portion of the district court's judgment.

Breach of contract

The interpretation of a contract is a matter of state law. *Power Lift, Inc. v. Weatherford Nipple-Up Sys., Inc., 871 F.2d 1082, 1085 (Fed. Cir. 1989).* A license [*1370] agreement is at its core a contract. In this case, both parties agree that New Jersey law governs their rights and obligations under the license, including the termination clause. Under New Jersey law, breach of contract is a question of fact properly reserved for a jury. *Magnet Res., Inc. v. Summit MRI, Inc., 318 N.J. Super. 275, 723 A.2d 976, 982 (N.J. Super. Ct. App. 1998).* Thus, the standard of review for this court is whether substantial [**39] evidence supports the jury's finding.

The jury found that "LabCorp breached the license agreement by terminating it" for the Abbott test. LabCorp contends that it did not formally terminate the contract, because the contract requires that the licensee provide written notice. The record contains no evidence of a written termination. The record does show, however, that LabCorp stopped paying royalties on the total homocysteine tests. Refusal to pay royalties is a material breach of the license. *See Dow Chem. Co. v. United States, 226 F.3d 1334, 1346 (Fed. Cir. 2000).* A material breach, in turn, constitutes termination even where the license agreement termination clause does not expressly so provide. *See Apex Pool Equip. Corp. v. Lee, 419 F.2d 556, 562 (2d Cir. 1969)* (holding that a licensee's material breach implicitly gives rise to a licensor's right to terminate); *see also Ross-Simons of Warwick, Inc. v. Baccarat, Inc., 217 F.3d 8, 10 (1st Cir. 2000)* ("Every contract involves a bargained-for exchange of obligations, the material breach of which by one party gives the other party a right to terminate."); *Restatement (Second) of Contracts § 237* [**40] *(1981).* This court, therefore, affirms the jury's finding that LabCorp breached the license agreement.

Enhanced damages

LabCorp does not directly challenge the jury's willfulness finding. Instead, LabCorp contends that the district court did not discuss the *Read* factors for enhanced damages. *See Read Corp. v. Portec, Inc., 970 F.2d 816, 826-27 (Fed. Cir. 1992), abrogated in part on other grounds, Markman, 52 F.3d at 975.* This court, therefore, addresses only the district court's grant of enhanced damages.

To be sure, this court has enunciated its strong preference that a district court set forth its rationale for an award of enhanced damages to facilitate appellate review. *Read, 970 F.2d at 828* ("To enable appellate review, a district court is obligated to explain the basis for the award, particularly where the maximum amount is imposed."). On the other hand, this court has also recognized the competing public policy of conserving judicial resources and has cautioned that a remand is a "step not taken lightly." *Consol. Aluminum Corp. v. Foseco Int'l Ltd., 910 F.2d 804, 814 (Fed. Cir. 1990)* (holding that [**41] a remand "should be limited to cases in which further action must be taken by the district court or in which the appellate court has no way open to it to affirm or reverse the district court's action under review"). As this court found in *Consolidated Aluminum*, "an appellate court need not close its eyes to the record where, as in this case, there is a way clearly open to affirm the district court's action." *Id. at 814.* Accordingly, this court considers the findings in the record for an abuse of discretion in doubling the infringement damages.

First, this court considers the second *Read* factor, namely whether LabCorp conducted an investigation regarding the scope of the *'658 patent* in order to form a good-faith belief. *Read Corp., 970 F.2d at 827.* LabCorp concedes that Dr. Wentz alone determined that the Abbott total homocysteine tests did not infringe the *'658 patent* and therefore LabCorp would not need to continue paying royalties to Metabolite. [*1371] Dr. Wentz himself testified during trial that his determination that the *'658 patent* did not extend to the Abbott total homocysteine tests was based solely on his interpretation of the license agreement [**42] between LabCorp and Metabolite. Moreover, Dr. Wentz testified that he did not consult the *'658 patent* itself. He also conceded his lack of training in patent law. Based on this evidence alone, the district court could easily have determined that LabCorp did not conduct a reasonable investigation into potential infringement by the Abbott total homocysteine tests. *See Underwater Devices Inc. v. Morrison-Knudsen Co., Inc., 717 F.2d 1380, 1390 (Fed. Cir. 1983)* (affirming district court's grant of enhanced damages where defendant obtained incompetent opinion from in-house counsel who was not a patent attorney, did not consult the patent file histories, and prepared a memo containing "only bald, conclusory and unsupported remarks regarding validity and infringement of the [] patents").

LabCorp's failure to conduct a reasonable and independent investigation regarding the Abbott total homocysteine test is further highlighted by the very terms of the license agreement between LabCorp and Abbott Labs. In the license agreement, Abbott Labs specifically excludes the *'658 patent* from a warranty covered by an indemnity provision. The warranty specifically excludes:

> Any claim [**43] of infringement which may arise under the subject matter of *U.S. Patent 4,940,658* and any U.S. or foreign patents claiming priority therefrom or otherwise related thereto. *Except with respect to the foregoing* and at the time of signing this Agreement, Abbott has no reasonable knowledge of any infringement of third party patent rights that would arise from the use of the Imx Homocysteine Research Assay.

(emphasis added). By accepting this provision, LabCorp knew or should have known that Abbott Labs believed the use of the Abbott test might infringe the *'658 patent.* This language in the license agreement would have put a reasonable licensee on notice to conduct its own investigation regarding the *'658 patent* coverage of the Abbott total homocysteine test.

In addition to the second *Read* factor, the record also reflects that LabCorp is a large company with extensive financial means, i.e., *Read* factor four. LabCorp's infringing activities of claim 13 began in 1998 without any attempts to remedy the infringement, *Read* factors six and seven, respectively. The district court therefore had evidence before it warranting consideration of at least four *Read* factors.

[**44] That the district court did not explicitly set forth its rationale for awarding Metabolite enhanced damages based on LabCorp's willful indirect infringement is not fatal to its decision. As in *Consolidated Aluminum*, "no useful purpose would be served by a remand to enable the district court to tell [this court] in express terms what [it] already knows from the record." *910 F.2d at 815*. On the basis of the appellate record, this court can readily discern at least four *Read* factors that the district court likely considered when using its discretion to double the infringement damages. Accordingly, this court holds that the district court did not abuse its discretion in enhancing the infringement damages. The district court's failure to discuss the *Read* factors, although contrary to this court's strong preference for the enumerated bases underlying its decision, in this case was at most harmless error.

Injunction

The district court granted Metabolite's motion "to enjoin LabCorp from performing ' [*1372] any homocysteine-only test, including without limitation homocysteine-only tests via the Abbott method.'"

LabCorp argues that the injunction is too broad because [**45] it extends beyond the scope of the claims. To the contrary, the injunction simply addresses LabCorp's specific acts constituting indirect infringement. LabCorp performs the assays upon request from physicians and in doing so indirectly infringes. The district court correctly enjoined LabCorp from infringement. LabCorp also argues that the injunction is defective in form under the Federal Rules of Civil Procedure, because *Rule 65(d)* requires that a district court "set forth the reasons" for issuing an injunction. The district court's order states that it "finds no sound reason for denying the injunction." While this statement does not explicitly set forth detailed reasons, the district court properly granted the injunction because LabCorp was found to infringe. *See W.L. Gore & Assocs., Inc. v. Garlock, Inc., 842 F.2d 1275, 1281 (Fed. Cir. 1988)* ("An injunction should issue once infringement has been established unless there is a sufficient reason for denying it."). The district court's brevity is not reversible error.

CONCLUSION

The district court did not err in denying JMOL, awarding enhanced damages, and granting the permanent injunction.

COSTS

Each party shall [**46] bear its own costs.

AFFIRMED

CONCUR BY: SCHALL (In Part)

DISSENT BY: SCHALL (In Part)

DISSENT

SCHALL, *Circuit Judge*, concurring-in-part, dissenting-in-part.

I agree with the majority's conclusions with respect to validity, the absence of a case or controversy regarding infringement of claim 18, breach of contract, enhanced damages, and the district court's injunction. However, I respectfully dissent from the majority's construction of claim 13 of the *'658 patent*. Because I think claim 13 covers only the correlation of elevated levels of homocysteine, I would remand the case for a recalculation of the damages resulting from indirect infringement.

Claim 13 of the *'658 patent* is an independent claim for a two-step method:

> 13. A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of:
>
> assaying a body fluid for an elevated level of total homocysteine; and
>
> correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.

Col. 41, ll. 58-65. Proper construction of the terms "correlating" and "elevated" is dispositive of the issue of infringement of claim 13. The district court construed [**47] "elevated" to mean "raised above the normal range," and "correlating" as "to establish a mutual or reciprocal relationship between." *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, No. 99-Z-870, slip op. at 2-3 (D. Colo. Nov. 29, 2000) (*Markman Order*). Disagreeing with neither of these constructions, the majority holds that when a patient's homocysteine level is not "elevated," claim 13 may nevertheless be infringed because "correlating" includes establishing both a mutual relationship and a reciprocal relationship. The majority states:

> In essence, "correlating" means to relate the presence of an elevated total homocysteine level to either a cobalamin or folate deficiency, or both (i.e., a mutual relationship), and also to relate the absence of an elevated total homocysteine level to a deficiency in neither [*1373] (i.e., a reciprocal relationship) . . . . The specification and prosecution history confirm that the claim language "correlating," in the understanding of one of ordinary skill in this art field at the time of invention, includes both a mutual relationship between the presence of an elevated level of homocysteine and a vitamin deficiency and a reciprocal relationship [**48] between the absence of an elevated level of homocysteine and no vitamin deficiency.

In my view, the majority impermissibly expands the scope of claim 13 beyond the actual words of the claim.

I begin with what I see as the controlling principles of claim construction. When interpreting the claims of a patent, the court should look first to the intrinsic evidence of record: the claim, the specification, and, if in evidence, the prosecution history. *Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)*. There exists within the intrinsic evidence a "hierarchy of analytical tools." *Digital Biometrics, Inc. v. Identix, Inc., 149 F.3d 1335, 1344 (Fed. Cir. 1998)*. First, the language of the claim should be considered--"the actual words of the claim are the controlling focus." *Id.* The claim language defines the bounds of claim scope. *Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 619-20 (Fed. Cir. 1995)*. Because the claims define the patentee's right to exclude others, "the claim construction inquiry, therefore, begins and ends in all cases with the actual words of the claim. [**49] " *Renishaw plc v. Marposs Societa' per Azioni, 158 F.3d 1243, 1248 (Fed. Cir. 1998)*.

If the meaning of a claim term is clear on its face, consideration of the remaining intrinsic evidence is restricted to determining if a deviation from the clear language of the claim is specified. *Interactive Gift Express, Inc. v. Compuserve Inc., 256 F.3d 1323, 1331 (Fed. Cir. 2001)*. The court may consider the patent specification in construing whether the patentee has intended for the meaning of a claim term to deviate from its ordinary meaning. *Vitronics, 90 F.3d at 1582*. The court may also consider the prosecution history, if it is in the record, for evidence of an intentional deviation from the plain meaning of a claim term. *Id.*

Beginning with the ordinary meaning of the claim terms, I too do not disagree with the district court's construction of the terms "elevated" and "correlating." Nor do I disagree with the majority's conclusion that the claim language does not require a further association between the level of total homocysteine and either a hematologic or neuropsychiatric abnormality or both. I cannot agree with the majority, however, [**50] that claim 13 is infringed when the test demonstrates that a patient's homocysteine level is *not* "elevated." The plain language of the claim requires "elevated" levels of homocysteine, and a heavy presumption weighs in favor of the ordinary and customary meaning of that term. *CCS Fitness v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002)*. As the district court properly construed the term, "elevated" requires a level of homocysteine that is "raised above the normal range." *Markman Order*, slip op. at 2-3. Thus, for claim 13 to be infringed, the homocysteine assay must evince a level of homocysteine that is raised above the normal range. In short, in my view the majority disregards the explicit limitation in claim 13 that only an "elevated" level of homocysteine can be "correlated" with a vitamin deficiency.

There is no language in claim 13 addressing unelevated levels of homocysteine, nor language that unelevated levels of homocysteine are to be correlated with the absence of a vitamin deficiency. Ordinary [*1374] meaning thus dictates that a patient's homocysteine level be "elevated" in order for a physician to practice claim 13. If the patient's homocysteine [**51] levels are not "elevated," by the plain language of the claim, there is no "correlating" to be done. The language of claim 13 does not suggest that the claim encompasses the correlation of unelevated levels with the absence of a deficiency, for the introductory phrase claims "a method for detecting a deficiency," without addressing at all the detection of the absence of a deficiency. *'658 patent*, col. 41, ll. 58-59.

We have repeatedly stated that "courts can neither broaden nor narrow claims to give the patentee something different than what he has set forth." *Texas Instruments v. United States ITC, 988 F.2d 1165, 1171 (Fed. Cir. 1993)* (quoting *Autogiro Co. v. United States, 181 Ct. Cl. 55, 384 F.2d 391, 396 (Ct. Cl. 1967))*; *Oak Tech., Inc. v. ITC, 248 F.3d 1316, 1329 (Fed. Cir. 2001)*. In this case, however, the majority has permitted claim 13 to be infringed even when homocysteine assays result in unelevated levels. The majority thereby broadens claim 13 to also include, although it is not expressly claimed, correlating unelevated levels of homocysteine with the absence of a vitamin deficiency.

Relying on language [**52] from the specification and the prosecution history, the majority brings assays that demonstrate unelevated levels of homocysteine within the province of claim 13 by focusing its construc-

tion on the term "correlating." The problem I have with this approach is that it ignores the term "elevated." In addition, because the term "elevated" in claim 13 is unambiguous on its face, the specification and prosecution history of the *'658 patent* may be consulted only to determine if the patentee intended to deviate from ordinary meaning. *Interactive Gift Express, 256 F.3d at 1331.* There is no evidence before us that any deviation was intended. Throughout the specification, the term "elevated" is consistently used to refer to levels that are raised above average. For example, the specification explains that

> The normal range for homocysteine in human serum is from about 7 to about 22 [mu]mol/liter. *Homocysteine levels above these ranges* are indicative of cobalamin and/or folate deficiency . . . .
>
> * * * *
>
> When homocysteine levels are *elevated* in individuals without inherited defects, at least one of folate or cobalamin is deficient.

'658 patent, col. 9, [**53] ll. 23-29, 38-40 (emphases added). Nor is there any evidence from the prosecution history that the patentee relinquished this claim construction in an amendment or in an argument to overcome or distinguish a prior art reference. *Vitronics, 90 F.3d at 1582.* Accordingly, I construe Claim 13 to require an assay that demonstrates an "elevated" homocysteine level, or one "raised above the normal range," in order for the claim to be practiced.

Pursuant to this claim construction, claim 13 is only infringed when the assays performed by LabCorp reveal elevated levels of homocysteine. As LabCorp explains, and as Metabolite does not dispute, approximately eighty to eighty-four percent of the assays LabCorp processes reveal unelevated levels of homocysteine. I would therefore vacate the jury's verdict that the assays resulting in unelevated levels of homocysteine infringed claim 13, and further vacate and remand the jury's verdict on damages for recalculation based only on those infringing assays that demonstrate elevated levels of homocysteine.

Source: USPQ, 2d Series (1986 - Present) > U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences > Ex parte Levy, 17 USPQ2d 1461 (Bd. Pat. App. & Int. 1990)

17 USPQ2d 1461

Ex parte Levy

U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences

No. 90-1864

Decided October 16, 1990

Headnotes

PATENTS

[1] Patentability/Validity - Anticipation - Identity of elements (▶ 115.0704)

Factual determination of anticipation requires disclosure in single reference of every element of claimed invention, and examiner must identify wherein each and every facet of claimed invention is disclosed in applied reference.

[2] Patentability/Validity - In general (▶ 115.01)

Patentability/Validity - Anticipation - Prior art (▶ 115.0703)

Initial burden of establishing prima facie basis to deny patentability rests upon examiner; examiner, if relying upon theory of inherency, must provide basis in fact and/or technical reasoning to reasonably support determination that allegedly inherent characteristic necessarily flows from teachings of applied prior art.

[3] Patentability/Validity - Anticipation - Prior art (▶ 115.0703)

Examiner erred by rejecting claims for biaxially oriented catheter balloon as anticipated by prior art which does not disclose such biaxially oriented balloon and which has not been shown to be inherently biaxially oriented.

[4] Patentability/Validity - Obviousness - Relevant prior art - Particular inventions (▶ 115.0903.03)

Examiner erred by rejecting claims for biaxially oriented balloon catheter under 35 USC 103 based upon combined disclosure of two prior art references, one of which was relied upon solely for disclosed use of high viscosity polyethylene terephthalate tubing and the other which was presupposed by examiner to disclose biaxially oriented catheter balloon, since examiner has not established that resulting catheter balloon using high viscosity tubing is biaxially oriented.

Case History and Disposition

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Application of Stanley B. Levy, serial no. 287,234, filed Dec. 21, 1988, which is a division of serial no. 914,108, filed Oct. 1, 1986, now Re. 32,983, granted July 4, 1989; and a reissue of serial no. 510,812, filed July 5, 1983, now patent no. 4,490,421, granted Dec. 25, 1984, for balloon and manufacture thereof. From examiner's rejection of claims 13 through 17 and 25 (James Seidleck, primary

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examiner), applicant appeals. Reversed.

Attorneys

Louis H. Rombach, Wilmington, Del., for appellant.

Judge

Before Steiner, Tarring, and J. Smith, examiners-in-chief.

Opinion Text

Opinion By:

Steiner, examiner-in-chief.

This is an appeal from the final rejection of claims 13 through 17 and 25, which are all of the claims remaining in this application for reissue of U.S. Patent No. 4,490,421.

The subject matter on appeal is directed to a polymeric balloon exhibiting properties which enable its use as a catheter balloon for medical dilation procedures, such as coronary angioplasty wherein a catheter with a balloon at a distal end thereof is inserted into coronary arteries and inflated. The balloon must be capable of exerting sufficient pressure to dilate stenotic lesions without rupture of the balloon.

Claims 13 and 25, the only independent claims on appeal, read as follows:

> 13. *High molecular weight, biaxially oriented, flexible polymeric balloon having a wall tensile strength of at least 31,714 psi (218.86 MPa).*
>
> 25. *High molecular weight, biaxially oriented, flexible polyethylene terephthalate dilatation catheter balloon.*

The references relied upon by the examiner are:

Wyeth et al. (Wyeth)	3,733,309	May 15, 1973
Schjeldahl et al. (Schjeldahl '989)[1]	4,413,989	Nov. 8, 1983
Schjeldahl et al. (Schjeldahl '000)[2]	4,456,000	June 26, 1984

[1] Each of the Schjeldahl references contains essentially the same relevant disclosure. Accordingly, unless otherwise indicated, we have referred to these references collectively as "Schjeldahl," consistent with the approach adopted by both appellant and the examiner.

[2] See footnote 1.

Claims 13, 14, 16, 17 and 25 stand rejected under 35 U.S.C. 102 as anticipated by Schjeldahl. Claims 13 through 17 stand rejected under 35 U.S.C. 103 based upon "Schjeldahl et al in view of Wyeth as set forth in the Final Rejection" (paragraph bridging pages 3 and 4 of the Answer). We reverse each rejection.

The Rejection of Claims 13, 14, 16, 17 and 25 Under 35 U.S.C. §102.

[1] The factual determination of anticipation requires the disclosure in a single reference of every element of the claimed invention. *In re Spada,* —F.2d —, 15 USPQ2d 1655 (Fed.Cir. 1990); *In re Bond,* —F.2d —, 15 USPQ2d 1566 (Fed.Cir. 1990); *Diversitech Corp. v. Century Steps, Inc.,* 850 F.2d 675, 7 USPQ2d 1315 (Fed.Cir. 1988); *Constant v. Advanced Micro-Devices, Inc.,* 848 F.2d 1560, 7 USPQ2d 1057 (Fed.Cir. 1988); *Alco Standard Corp. v. TVA,* 808 F.2d 1490, 1 USPQ2d 1337 (Fed.Cir. 1986); *In re Marshall,* 578 F.2d 301, 198 USPQ 344 (CCPA 1978); *In re Arkley,* 455 F.2d 586, 172 USPQ 524 (CCPA 1972). Moreover, it is incumbent upon the examiner to identify wherein each and every facet of the claimed invention is disclosed in the applied reference. *Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick,* 730 F.2d 1452, 221 USPQ 481 (Fed.Cir. 1984).

Each of the independent claims on appeal defines a polymeric balloon which is "biaxially oriented." Ergo, in order to establish a *prima facie* basis to defeat the patentability of independent claims 13 and 25 under 35

U.S.C. §102, the examiner is obliged to point out where Schjeldahl discloses a *biaxially oriented* polymeric balloon. The tenor of the final rejection and Answer presupposes that Schjeldahl discloses a biaxially oriented polymeric balloon. See, for example, page 5 of the Final Rejection wherein the examiner states

> he reference clearly teaches a biaxially oriented balloon catheter, and states that it is made by injection blow molding.

See, also, page 5 of the Answer wherein the examiner states

> rguments that the references don't disclose a biaxially oriented PET (polyethylene terephthalate) balloon catheter is contrary to what is *clearly stated* in the references (emphasis supplied).

The examiner does not point to, and we do not find, any express disclosure in Schjeldahl of a biaxially oriented polymeric balloon.

It would appear that the relevant evulgations in Schjeldahl which may have led the examiner to his determination are:

> (a) an expander [3] formed *from* a thin, flexible inelastic, high tensile strength, *biaxially oriented* synthetic plastic material
>
> **Page 1463**
>
> (column 2 of Schjeldahl '989, lines 63 through 65, emphasis supplied);

[3] Schjeldahl characterizes the catheter balloon as an expander.

> (b) The expander 30 is preferably formed *from* a suitable synthetic plastic material, such as *biaxially oriented* polypropylene, *by an injection blow molding operation* and, as such, is substantially inelastic in both the axial and radial directions and may, for example, have a finished wall thickness in the range of from 0.005 to 0.200 millimeters, 0.025 millimeters being typical (column 6 of Schjeldahl '989, lines 45 through 52, emphasis supplied);
>
> (c) It has been found that an expander of the above-dimensional characteristics can withstand internal inflation pressure in excess of 7 atmospheres without fear of rupture (column 6 of Schjeldahl '989, lines 62 through 65);
>
> (d) injection blow molding step used to form the expander 30 (column 8, lines 16 and 17);
>
> (e) the expander 30 is formed *from* a *biaxially oriented* thin plastic material capable of withstanding relatively high internal pressures without rupture and without exceeding the elastic limit for the material itself (column 10 of Schjeldahl '989, lines 32 through 36, emphasis supplied);
>
> (f) the expander 82 is preferably formed *from* a suitable synthetic plastic material such as *biaxially oriented polypropylene* or *biaxially oriented polyethylene terephthalate by an injection molding operation* and, as such, is substantially inelastic in both the axial and radial direction (column 12 of Schjeldahl '989, lines 22 through 37, emphasis supplied); and
>
> (g) Apparatus as in claim 1 wherein said non-elastic expander member comprises a longitudinally extending thin, flexible, tubular element *formed from a biaxially oriented* synthetic plastic material surrounding said outer tubular member with opposed ends thereof secured to said outer tubular member at spaced apart locations proximate said distal end thereof (claim 8 of Schjeldahl '989, emphasis supplied).

These excerpts do not justify the determination that Schjeldahl discloses a biaxially oriented polymeric balloon.

According to Schjeldahl, the *starting* material is a biaxially oriented synthetic plastic material, such as polyethylene terephthalate. The *final article, i.e.,* the expander or catheter balloon, is *not characterized as biaxially oriented.* Moreover, it would appear to be *undisputed* that the *only* method disclosed by Schjeldahl for transforming the biaxially oriented *starting* plastic into the *final* catheter balloon, *i.e.,* injection blow molding, is *not* capable of producing a biaxially oriented catheter balloon. In fact, it is *undisputed* that injection blow molding would *destroy* the biaxial orientation of the plastic starting material. We refer to the Belcher affidavits, Exhibits V, VI and VIII, [4] which factually set forth the differences between "injection blow molding" and "injection stretch blow molding," and support the conclusion that the "injection blow molding" process disclosed by Schjeldahl could not possibly produce a biaxially oriented polymeric balloon. [5]

[4] Unless otherwise indicated, all exhibits mentioned are the exhibits to appellant's Brief.

[5] We recognize that a high burden of proof is required to demonstrate the inoperability of a United States patent. *In re Weber,* 405 F.2d 1403, 160 USPQ 549 (CCPA 1969); *In re Michalek,* 162 F.2d 229, 74 USPQ 107 (CCPA 1947). However, as noted above, Schjeldahl does not disclose a catheter balloon made *of* a biaxially oriented plastic. Therefore, appellant's evidence is not an attack on the

operability of Schjeldahl, but quite relevant to the issue of inherency, *i.e.*, whether the catheter balloon disclosed by Schjedahl is inherently biaxially oriented.

Indeed, the examiner agrees with appellant's position that injection blow molding could *not* produce a biaxially oriented balloon. See, for example, page 5 of the Final Rejection wherein the examiner states:

> tatements that injection blow molding without stretching will not produce a biaxially oriented article are *true* ... (emphasis supplied).

The examiner goes on, in the same sentence, to state:

> but since the reference produces a biaxially oriented article, clearly a stretching step must be used.

Again, on page 5 of the Answer, the examiner states:

> Since Schjeldahl et al produces a biaxially oriented article it follows that a stretching step must be used in the injection blow molding process.

The inescapable facts are that Schjeldahl does not disclose a biaxially oriented catheter balloon and does not mention a stretching step.

[2] The examiner also relies upon the theory that Schjeldahl's catheter balloon is inherently biaxially oriented. On page 4 of the Answer, the examiner points out that inasmuch as the Patent and Trademark Office does not have the requisite laboratory equipment for testing, the burden shifts to appellant. However, the initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention rests

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upon the examiner. *In re Piasecki,* 745 F.2d 1468, 223 USPQ 785 (Fed.Cir. 1984). In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art. *In re King,* 801 F.2d 1324, 231 USPQ 136 (Fed.Cir. 1986); *W.L. Gore & Associates, Inc. v. Garlock, Inc.,* 721 F.2d 1540, 220 USPQ 303 (Fed.Cir. 1983); *In re Oelrich,* 666 F.2d 578, 212 USPQ 323 (CCPA 1981); *In re Wilding,* 535 F.2d 631, 190 USPQ 59 (CCPA 1976); *Hansgirg v. Kemmer,* 102 F.2d 212, 40 USPQ 665 (CCPA 1939). In our opinion, the examiner has not discharged that initial burden.

Schjeldahl does not provide any working example revealing the process conditions employed to produce the catheter balloon. We have *only* a general invitation to employ "injection blow molding." As previously discussed, it is undisputed that injection blow molding would *not* have produced a biaxially oriented balloon and would have destroyed the biaxially orientation of a polymeric starting material.

Schjeldahl does not disclose any particular tensile strength of the catheter balloon. We do not find sufficient factual basis or cogent scientific reasoning to support the conclusion that Schjeldahl's disclosure with respect to the ability of the catheter balloon to "withstand an internal inflation pressure in excess of 7 atmospheres without fear of rupture" (column 6 of Schjeldahl '989, lines 63 through 65) *necessarily* means that the catheter balloon is biaxially oriented. According to the membrane equation calculations reported in Levy's declaration (Exhibit IV), Schjeldahl's balloon could not possibly exhibit the tensile characteristics of a biaxially oriented balloon. Levy's calculations are *inconsistent* with those of Pinchuk (Exhibit III). Suffice it to say, the conflicting calculations taint the factual determination of inherency with impermissible conjecture. Indeed, the examiner, in the paragraph bridging pages 4 and 5 of the Answer, states that

> the membrane equation used to determine the tensil [sic, tensile] strength can be manipulated to produce any desired value, and thus is misleading.

Nevertheless, the examiner goes on to favor Pinchuk's calculations by stating in that same paragraph that

> ertainly use of the typically used wall thickness disclosed in Schjeldahl et al with the average radius, as done in the Pinchuk Declaration would be reasonable.

As noted above, the conflicting results obtained by applying the membrance equation, and the examiner's acknowledgment that that equation "can be manipulated to produce any desired value," underscore the speculative nature upon which the determination of inherency rests.

We do not find sufficient cogent technical reasoning and/or objective evidence to support the conclusion that Schjeldahl's characterization of the catheter balloon as inelastic in the axial and radial direction *necessarily* means that the catheter balloon is biaxially oriented. The characteristic "inelastic," as employed by Schjeldahl, apparently means that the catheter balloon will expand to a preformed diameter to enable precise measurement of the pressures exerted on the inner wall of the artery during the dilation procedure (column 4 of Schjeldahl '989, lines 12 through 17).

[3] In summary, Schjeldahl does not disclose a biaxially oriented catheter balloon. We do not find a sufficient basis to support the determination that Schjeldahl's balloon is *inherently* (necessarily) biaxially oriented. *In re King, supra; W.L. Gore & Associates, Inc. v. Garlock, Inc., supra; In re Oelrich, supra; In re*

Wilding, supra; Hansgirg v. Kemmer, supra. Accordingly, the examiner's rejection of claims 13, 14, 16, 17 and 25, under 35 U.S.C. §102 as anticipated by Schjeldahl is *reversed.* [6]

[6] There is evidence of record that Dupont, the assignee of the application, furnished biaxially oriented polyethylene terephthalate to Schjeldahl when he informed Dupont personnel that he required a thin, high strength polymeric film having a tensile strength in the range of 20,000-40,000 psi. See the Schjeldahl affidavit (Exhibit VIII) and the Dengler declaration executed on May 21, 1988 and appended to the protest submitted in parent application Serial No. 914,108. Such facts are not inconsistent with our determination that Schjeldahl does not disclose a biaxially oriented polyethylene terephthalate catheter balloon. The Rydell affidavit appended to the protest in the parent application does not persuade us that Schjeldahl expressly or inherently discloses a biaxially oriented polymeric catheter balloon. See Belcher's affidavit (Exhibit VI).

The Rejection of Claims 13 through 17 under 35 U.S.C. §103 Based upon the Combined Disclosures of Schjeldahl and Wyeth.

Wyeth is directed to producing high strength biaxially oriented polyethylene terephthalate beverage containers. The disclosed method involves stretching polyethylene terephthalate having a relatively high inherent viscosity; *e.g.,* at least about 0.85.

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It is apparent from the Final Rejection and Answer that the examiner's rejection of the appealed claims under 35 U.S.C. 103 is *not* predicated upon the theory that one having ordinary skill in the art would have been led to employ Wyeth's technique to produce a biaxially oriented balloon for use in Schjeldahl's catheter. Instead, the examiner presupposes that Schjeldahl discloses a biaxially oriented catheter balloon. The examiner relies upon Wyeth *solely* for the disclosed use of high viscosity polyethylene terephthalate tubing. We refer to page 6 of the Answer, first complete paragraph, wherein the examiner explains the rejection by stating:

> Wyeth et al is not being combined with Schjeldahl et al, but merely shows the claimed high viscosity PET (polyethylene terephthalate) and supports the examiners [sic, examiner's] inherency arguments. [7] ... The examiner is not substituting the process of Wyeth et al into Schjeldahl et al since both disclose the same process. [8] Arguments that Wyeth et al can't be scaled down are irrelevant since the examiner is not seeking to scale down that reference to produce the claimed article.

[7] Actually, according to the Final Rejection which is incorporated in the Answer,

> t is the Examiner's position that it would be *prima facie* obvious to use the high viscosity polyethylene terephthalate of Wyeth in Schjeldahl et al to produce the claimed product (page 4, the only complete paragraph).

[8] It is apparent from our reversal of the examiner's rejection under 35 U.S.C. §102 that, in our opinion, Schjeldahl discloses neither a biaxially oriented catheter balloon nor a molding process which involves stretching.

[4] We have already concluded that the examiner factually erred in determining that Schjeldahl expressly or inherently discloses a biaxially oriented catheter balloon. Assuming, *arguendo,* the examiner correctly concluded that one having ordinary skill in the art would have been led to employ a high viscosity polyethylene terephthalate tubing in producing Schjeldahl's catheter balloon, the rejection under 35 U.S.C. §103 must fall because the examiner has not established that the resulting catheter balloon is biaxially oriented. *Uniroyal, Inc. v. Rudkin-Wiley Corp.,* 837 F.2d 1044, 5 USPQ2d 1434 (Fed.Cir. 1988).

Inasmuch as the examiner's rejection under 35 U.S.C. §103 is not predicated upon the theory that one having ordinary skill in the art would have been led to employ a conventional stretch blow molding technique, such as that disclosed by Wyeth, to produce Schjeldahl's catheter balloon, the motivation for such a combination is an issue which was not crystallized on appeal and was not confronted by appellant. However, in view of the examiner's gratuitous statement in the paragraph bridging pages 5 and 6 of the Answer, [9] we are constrained to address that issue.

[9] The noted statement provides:

> Certainly in the least there was an *invitation* to make a biaxially oriented catheter balloon at the time of the Schjeldahl et al invention. Additionally injection stretch blow molding to produce biaxially oriented articles was well known at the time of the Schjeldahl et al invention (emphasis supplied).

There appears to be no dispute that one having ordinary skill in the art would have recognized the desirability

of producing a biaxially oriented balloon for use in Schjeldahl's catheter, since biaxially oriented materials were known to exhibit high tensile strengths. The thrust of the evidence relied upon by the examiner is that one having ordinary skill in the art would have simply resorted to a conventional stretch molding technique to produce a biaxially oriented balloon for use in Schjeldahl's catheter, specifically, *the technique employed by Wyeth to produce a beverage container.* See paragraph 4 of the Rydell affidavit executed April 25, 1988 and offered in support of the protest in parent application Serial No. 914,108, paragraph 5 of the Pinchuk affidavit (Exhibit III), and paragraphs 4 and 5 of the Kaufman affidavit (Exhibit XII). Interestingly enough, *Wyeth disagrees.* See page 5 of Wyeth's declaration (Exhibit XI). Wyeth points out various differences between the PET bottles produced by his disclosed process and the requirements of a catheter balloon, and then concludes that his process could *not* be used to produce a catheter balloon of the type disclosed by Levy.

We are persuaded by Belcher's affidavits and Wyeth's declaration, notwithstanding the affidavits of Rydell, Pinchuk and Kaufman, [10] that the known processes for producing

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biaxially oriented beverage containers, such as that disclosed by Wyeth, could not have been simply scaled down to produce a biaxially oriented catheter balloon for use in medical dilation procedures without the exercise of inventive skill. [11] Based upon the record before us, it would appear unrealistic to conclude that one having ordinary skill in the art would have been led to employ Wyeth's technique, which is designed to produce beverage containers, to produce Schjeldahl's catheter balloon, motivated by a *reasonable expectation* of obtaining a *biaxially oriented* polymeric catheter balloon. *In re O'Farrell,* 853 F.2d 894, 7 USPQ2d 1673 (Fed.Cir. 1988). The rejection under 35 U.S.C. §103 is also *reversed.*

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[10] We agree with appellant that the credentials of Belcher and Wyeth in the relevant art appear more impressive than those of protestor's experts. According to the affidavit appearing as Appendix V, Belcher authored the chapter called "Blow Molding of Polymers" for the fifth edition of the Plastic Engineering Handbook of the Society of Plastics Industry. In addition, Belcher authored two chapters, one on "injection blow molding" and one on "stretch blow molding" for the Blow Molding Handbook of the Society of Plastics and Engineers. We consider Wyeth's opinion with respect to the capabilities of his own invention entitled to greater weight than the opinions of Rydell, Pinchuk and Kaufman.

[11] We find it somewhat unrealistic in light of the apparent disparities in size and function, Belcher's affidavits and Wyeth's declaration, that Pinchuk and Kaufman equate beverage bottles to catheter balloons. See paragraph 10 of the Pinchuk affidavit (Exhibit III), wherein it is stated

> s a blow molded polymeric article, a bottle and a catheter balloon are equivalent.

See, also, paragraph 4 of the Kaufman affidavit (Exhibit XII), wherein it is stated that

> anyone with ordinary skill in the plastics art would know how to make a biaxially oriented PET balloon; it would be similar to making a biaxially oriented PET bottle because both catheter balloons and bottles are equivalent structures - they are both fluid containers.

REVERSED.

- End of Case -